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Precision and Accuracy: Omnipod Pdm® (O-Pdm) Versus Freestyle Lite Meter® (Fsl Meter) Utilizing Freestyle Lite (Fsl)® Test Strips in Multiple Patient Situations

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PRECISION AND ACCURACY: OMNIPOD PDM® (O-PDM) VERSUS FREESTYLE LITE METER® (FSL METER) UTILIZING FREESTYLE LITE (FSL)® TEST STRIPS IN MULTIPLE PATIENT SITUATIONS

by
Christine Marianthi Hayden

A thesis submitted to the faculty of The University of Mississippi in partial fulfillment of the requirements of the Sally McDonnell Barksdale Honors College.

Oxford
May 2013

Approved by

_____________________________
Advisor: Dr. David B. Murray

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Reader: Dr. Matthew Strum

_____________________________
Reader: Dr. Donna West-Strum
This thesis is dedicated to my grandmother, Yia Yia. Thank you for letting me drop out of pre-school; I don’t know where I would be without you. Thank you for teaching me the value of education and teaching me that it is something that no one can ever take away from you. You have been my role model for 22 years and I cannot thank you enough. This thesis is also dedicated to my family, who without them, I would have never made it this far.
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ABSTRACT

CHRISTINE MARIANTHI HAYDEN: Precision and Accuracy: O-PDM versus FSL meter Utilizing FSL Test Strips in Multiple Patient Situations (Under the direction of Dr. David B. Murray)

Today, diabetes mellitus affects 8.3% of the people in the United States and is having detrimental effects on patient populations as well as health care. To this date, there are numerous monitors that all meet specific requirements and industry standards in order to aid patients in self-monitoring of blood glucose (SMBG). There is currently a large market for these monitors and efforts have been made to devise the monitors to be accurate and precise. Through this study, accuracy and precision were studied by evaluating the difference between the O-PDM and FSL meter monitoring systems. It was hypothesized that a difference in accuracy and precision may or may not occur when scented and unscented lotion residues are placed on the testing sites before glucose readings. By taking glucose readings with lancets at multiple sites using FSL test strips with both O-PDM and FSL meter monitors and then taking readings again once lotion residues were removed with alcohol, data were analyzed to determine if a change was present. It was concluded that changes were apparent when scented lotion and unscented lotion was present on the testing site. In addition, a statistically significant difference was present in the unscented lotions of both the O-PDM and FSL meter groups when compared to their respective controls. The alcohol data showed large differences when compared to the readings taken with lotion present, and the alcohol group presented data that was similar to the control groups. By understanding potential sources of error, such as lotion residues as well as other left over particles, health care professionals, as well as patients may utilize SMBG more effectively. The importance of hand washing as well as
cleaning testing sites with alcohol before readings is encouraged for both patients and health care professionals in order that they may identify common errors and work towards improved diabetes care.
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INTRODUCTION

Diabetes mellitus is a metabolic disorder that is characterized by a condition where the quantity of blood glucose is elevated above normal, which is clinically termed hyperglycemia. Consequently, the resulting buildup of glucose is excreted in the urine. Although the blood contains plenty of glucose, the cells of the body are unable to properly grow, or efficiently utilize glucose for energy needs due to the altered production or sensitivity to the major glucose regulating hormone insulin. There are two types of diabetes, type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM). T1DM, formerly called insulin-dependent diabetes mellitus (IDDM), develops from autoimmune disorders, environmental factors, or genetic disorders which affect the pancreas gland and cause little or no insulin to be produced. This is why patients with T1DM must take insulin in order to survive. Risk factors that accompany T1DM are less common than those for T2DM. Currently, 5% of all diagnosed cases account for T1DM.

T2DM, formerly called non-insulin-dependent diabetes mellitus (NIDDM), account for 90-95% of all diagnosed cases of diabetes. Insulin, in this case, is made in sufficient amounts but the cells of the body fail to respond to the insulin that is being produced (i.e. insulin resistant syndrome). Those affected with T2DM have risk factors such as family history of diabetes, race, ethnicity, prior history of gestational diabetes, lowered glucose tolerance (the inability to properly metabolize glucose), lack of physical activity, and obesity. β-cells in both T1DM and T2DM have progressive failure, leading to apoptosis, or cell death. β-cells are responsible for synthesizing, packaging, and secreting insulin. Thus, the loss of cells that produce insulin lead to the loss of ability
of the cells to promote glucose uptake.\textsuperscript{3,4} In T1DM, $\beta$-cells are destroyed by the immune system.\textsuperscript{3,4} Because of the destruction of $\beta$-cells, insulin cannot be produced, and therefore, the glucose stays in the blood instead of being used for the needed metabolic processes.\textsuperscript{3,4} In T2DM, $\beta$-cells are still being made and processed but the body is desensitized to insulin and a resistance develops.\textsuperscript{3,4} The insulin receptors that are located on the membranes of the liver and muscle cells lose their ability and are uncoupled to the normal process of $\beta$-cells with respect to insulin.\textsuperscript{3,4} The normal glucose levels for someone not affected with diabetes are as follows: 80–120 mg/dl before meals, $\leq$160 mg/dl two hours after meals, and 100 mg/dl to 140 mg/dl at bedtime.\textsuperscript{5} The classification for diabetes is impaired glucose tolerance (IGT) between 140 and 199 mg/dl; IGT is evaluated as a 2-hour post-meal glucose level.\textsuperscript{6} IGT is defined as a transition phase between normal glucose levels and levels found in a patient with diabetes.\textsuperscript{6} Those with IGT do not have diabetes, but are considered to be in the “at risk category” of prediabetic.\textsuperscript{6} In addition, impaired fasting glucose (IFG) is a classification for diabetes mellitus and patients at risk have blood glucose levels between 110 mg/dl and 125 mg/dl.\textsuperscript{6} IFG is elevated blood glucose levels in the morning before eating or drinking.\textsuperscript{6} The current fasting criteria used for diagnosis is blood glucose of 126 mg/dl, which is equivalent to 7.0 mmol/l.\textsuperscript{6} The International Expert Committee on the Diagnosis and Classification of Diabetes Mellitus altered the fasting diagnosis criteria from 140 mg/dl to 126 mg/dl in 2004 in hopes of diagnosing diabetes mellitus earlier, which could ultimately lower chances of acute and chronic complications from diabetes.\textsuperscript{7} It is vital that patients work with health care teams to maintain and control healthy lifestyles, especially in an era when diabetes mellitus is on the frontier of healthcare issues.
Today, diabetes is prevalent amongst the nation especially the southeast, in particular, the state of Mississippi. According to the American Diabetes Association (ADA), 25.8 million children and adults in the United States, or approximately 8.3% of the U.S. population, are affected with diabetes. Of this 8.3%, 18.8 million people are diagnosed and 7.0 million people are undiagnosed. In addition, 79 million people in the U.S. have prediabetes. Using fasting glucose and A1C levels, the ADA identified 1.9 million new cases of diabetes in patients 20 years and older in the year 2010. More specifically, of patients <20 years, about 1 in every 400 children and teenagers have diabetes. There are 25.6 million patients ≥20 years affected with diabetes and 10.9 million people age ≥65 years with diabetes. Men and women are approximately equal when compared with the prevalence of diabetes; 13.0 million, or 11.8% of all men aged ≥20 years have diabetes, while 12.6 million, or 10.8% of all women aged ≥20 years have diabetes. However, race and ethnic differences are a factor in the prevalence of diagnosed diabetes. According to a 2007-2009 national survey where population age differences are adjusted, diagnosed diabetes is as follows: 7.1% of non-Hispanic whites, 8.4% of Asian Americans, 12.6% on non-Hispanic blacks, and 11.8% of Hispanics. With diabetes comes an increased risk of secondary complications that could lead to life threatening conditions. In 2007, diabetes was listed as the underlying cause on 71,383 death certificates, and was listed as a contributing factor on an additional 160,022 death certificates. In total, 231,404 deaths were attributed to diabetes. In addition, diabetes accounts for multiple complications to include: heart diseases and stroke, high blood pressure, blindness, kidney disease, neuropathy, and lower extremity amputation.
The southeastern U.S. has earned the distinction as the nation’s “diabetes belt.”

Fifteen different states (clustered in 644 counties) show a clear trend of high diabetes rates and include the following: Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, North Caroline, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, Virginia, West Virginia, and the entire state of Mississippi. According to the health surveys conducted by the Center for Disease Control and Prevention (CDC), the southeast region is more likely to be obese and have a sedentary lifestyle than any other area of the U.S. One-third of the difference in diabetes rates can be accounted for these lifestyle factors in the southeast region. In addition, the “diabetes belt” contains a greater amount of patients over the age of 65 years and a greater number of African Americans. These two populations are considered a “higher risk” population for diabetes mellitus. According to Reuters Health, “we suspect that there are cultural factors that are very hard to measure, for example traditional diets or attitudes toward seeking medical care.” Most alarming is the fact that the “diabetes belt” overlaps with the “stroke belt” and the “heart failure belt.” In addition, it is estimated that the statistics of the “diabetes belt” are underestimated since many patients polled may have been undiagnosed.

Within the southeast, diabetes in Mississippi has devastating effects on the healthcare of its population. Mississippi has the highest rate of obesity (24.3%) and the highest rate of diabetes (8.8%) when compared with the rest of the U.S. In Mississippi there are 1,600 deaths per year that are contributed to diabetes. In 2002, approximately 270,000 Mississippians had diabetes, one-third of which were undiagnosed. About 1,700 Mississippians suffer from complications associated with diabetes each year.
The estimated cost of diabetes in the state of Mississippi is approximately $1.7 billion per year.\textsuperscript{11} A recent study conducted by Kaiser Permanente recorded that 12.4\% of adults have been told that they have diabetes in the state of Mississippi compared to 9.5\% in the U.S in the year 2011.\textsuperscript{12} In 2009, the number of diabetes related deaths per 100,000 was 29.2 in Mississippi compared to 20.9 in the U.S. In 2012, Mississippi was ranked as the 50\textsuperscript{th} state for the most affected people with diabetes mellitus and the 49\textsuperscript{th} state ranked for lack of overall health.\textsuperscript{12} Each year the health disparities of Mississippi progressively worsen. It is imperative that diabetes education, as well as overall health care education must be enforced in Mississippi if any progress or prevention will be made.

\textit{Precision and Accuracy}

To date, there are numerous glucose monitors that all meet specific requirements and industry standards. It has been the goal of manufacturers that patients can use smaller volumes of blood to gauge blood glucose to limit the severity of skin pricks, since patients affected with diabetes must prick their skin multiple times a day. There is currently a large market for these monitors and efforts have been made to devise the monitors to be accurate and precise. According to the Merriam-Webster dictionary, accuracy is defined as the “degree of conformity of a measure to a standard or a true value.”\textsuperscript{14} In addition, precision is defined as, “the degree of refinement with which an operation is performed or a measurement stated.”\textsuperscript{14} However, glucose monitors are now being coupled with other aspects of treatment. For example, the Omnipod Insulin Management System® aims to aid patients in the ease of diabetes management care.\textsuperscript{15} The Insulet OmniPod Insulin Management System®, also known as the “patch pump,” is
the first commercially available pump that is a fully integrated and wearable pump. The system is a vital part of the Artificial Pancreas Project that is sponsored by the Juvenile Diabetes Research Foundation. The pump is controlled wirelessly with a handheld device that contains a built-in blood glucose meter. The Insulet Omnipod Management System® consists of two components: the OmniPod Personal Diabetes Manager (PDM)® and the OmniPod Disposable Infusion Pump (Pod)®. The PDM integrates Abbott’s FreeStyle® blood glucose meter. The Pod is used by being worn directly on the body through an adhesive base. The Pod delivers insulin through an integrated soft cannula that is delivered to the subcutaneous tissue automatically. The Pod contains an insulin reservoir that stores 200 units of U-100 insulin. To assess the accuracy of the O-PDM, seven O-PDMs were tested at bolus doses of 0.5, 0.1, 0.2, 1, and 6 U. The delivered volumes and variability were analyzed. At the dose of 5 U, the devices were accurate and precise with less than 5% error for all of the devices. However, this accuracy was not true for doses that were smaller (1 U and 2 U). By comparing two methods of delivery, it was concluded that the O-PDM is extremely precise with a relative error of -0.9% to 0.96% for all of the studied doses. The O-PDM is not widely studied and is still in the process of being evaluated for its full precision and accuracy in clinical settings. Within this study, I evaluate the O-PDM and Abbott Diabetes Care FSL meter blood glucose monitoring system.

FSL blood glucose monitoring systems were introduced in 2000 to improve the accuracy and precision of self-monitoring for patients affected with diabetes. FSL systems require 3μl of blood sample to perform a test and offer alternate testing sites. One of the main features of the FSL systems is that the dual fill indicator electrodes
arranged across the fill channel allow the desired amount of blood sample is provided to the strip before a completed reading of the assay, therefore, minimizing potential test errors. In addition, the FSL system uses coulometry technology to measure glucose, which utilizes the total charge generated from the glucose reaction in the sample to perform a glucose measurement. Also, FSL utilizes a low potential for the oxidation of the mediator in order to decrease and minimize interferences that may be caused by acetaminophen, ascorbic acid, and uric acid. Abbott Diabetes Care developed the FSL blood glucose monitors that require no-coding test strips; the meters are preconfigured and pre-calibrated representative of the strip. No-coding FSL strips have the potential to minimize clinical inaccuracy by allowing the slope and intercept to have finite ranges and thus decrease interferences. The precision of the FSL meter system was analyzed by evaluating heparinized venous blood samples at five glucose levels. In total, three lots of test strips and 16 FSL meters were used. Ten repeated tests were performed on each meter for each glucose level and test strip lot. The standard deviation of the averaged three strip lots was 2.8-3.9 mg/dl (0.16-0.22 mmol/liter) at glucose concentrations <100 mg/dl (<5.56 mmol/liter) and the coefficient of variation was 3.9-5.0% at glucose concentrations ≥100 mg/dl (≥5.56 mmol/liter).

Through these performed tests, clinicians and diabetes management teams are able to decide whether or not this meter is suitable for their patients. The data provide evidence that may aid in determining the precision and accuracy of the meters, and thus, tighter glycemic control for patients. Through the dual-fill indicators across the fill channel, no-coding test strips and coulometry technology, the FSL system minimizes inaccuracies and variations that may be present in clinical settings. By studying the
differences between the two, a change in readings between the systems may or may not occur.

Although glucose monitoring is an integral part of patient care, limitations in accuracy are present. Although a monitor may be precise, it may not be accurate; thus it may skew results, and ultimately, patient treatment. The International Organization of Standardization defined accuracy as “the difference between the expectation of measurement results and the true value of the measured quantity.” The ADA has suggested that SMBG systems be developed to achieve an analytical plus a user error of <10% at BG levels between 30 and 400 mg/dl. The analytical error goal for such SMBG systems is 5% or less. An error up to 5% of the results can be medically unacceptable, and it is reported that SMBG systems needs to have an inaccuracy no >2% to avoid excessive hypoglycemia or hyperglycemia.

The total error present in SMBG is the difference between the observed value and the true glucose value. Total error may include: pre-analytic, analytic, and post-analytic errors. Analytic errors are the most crucial to patient education and are classified into the four following categories: imprecision, random patient interference, protocol-independent bias, and protocol-dependent bias. Patient interference may be due to factors such as improper coding, altered hematocrit, naturally occurring interfering substances, and incorrect hand washing. Specifically, hand washing has always been a problem. Today, micro sample meters can detect the smallest amount of contaminant resulting in falsely elevated or low blood glucose. Since patients normally do not wash their hands before monitoring, contamination can be a major source of inaccuracy. Several standards have been proposed, however, a consensus about how to measure blood
glucose meter accuracy has not been developed. Therefore, a change in accuracy and precision may result in confounding factors such as: accuracy of the machine, lotion residues, or residual food particles. By testing the accuracy of the O-PDM with the FSL meter with scented and unscented lotions, a change in readings and measurements may or may not be attained. With the removal of left over lotion particles with alcohol, readings can be evaluated for precision and accuracy. By understanding the source of error and methods of prevention, health care providers can help patients’ utilization of SMBG systems more effectively. We believe improvements in analytical accuracy ultimately lead to an improvement in clinical outcomes for patients.

SMBG allows diabetes care to be effective not only for health care professionals, but also ultimately for the affected patient. Because each monitor and test strip is different and unique to the patient, it is of great importance that the patient is aware that accuracy may not always equal precision. Therefore, we sought to evaluate confounding factors on the side of the patient as well as question of accuracy versus precision of the side of the monitors (O-PDM versus FSL meter).
MATERIALS AND METHODS

This study, “Precision and Accuracy: O-PDM versus FSL meter Utilizing FSL Test Strips in Multiple Patient Situations” was reviewed by the Institutional Review Board (IRB) at The University of Mississippi and approved (IRB Protocol #12-315). Through the University of Mississippi Bulletin Boards, an email was sent to specific groups looking for participation in the study. Participants over the age of 18, without known diabetes mellitus, were recruited as subjects. Each participant was given a randomized code to keep his or her anonymity; the participants were not required to come fasting. The investigator wore latex gloves, and used a new pair of latex gloves between each quadrant reading. The laboratory used was sanitized before every use and covered with proper tablemats. The participant was asked to wash either their left or right forearm with soap and water and to dry their forearm with a clean, dry paper towel. Next, the investigator divided the subject’s forearm into three quadrants using a black, wax pencil. At the top quadrant, unscented lotion (Curel® fragrance free moisturizer) was saturated on their skin and allowed to dry. The middle section was utilized as the control. The bottom/lower quadrant was saturated with scented lotion (Curel® scented moisturizer) and allowed to dry. The quadrants with lotion were then given a second layer of indicated lotion (scented or unscented) and allowed to dry before readings were gathered. Once these lotions had been absorbed, the subject was prepped for glucose readings. The investigator used Accu-Check Safe-T-Pro Plus® lancets for each quadrant. A lancet is a device similar to a small needle and used in standard diabetes care for both fingertip and alternate testing sites, to include the forearm. The lancet has three depths settings (1.3 mm, 1.8 mm and 2.3 mm). The 2.3 mm setting was utilized in this study due
to forearm evaluation. The investigator lanced the subject’s top quadrant (unscented lotion). The investigator, using FSL test strips, read the blood glucose readings by using first, the FSL monitor, then with another FSL test strip read a second reading (from the same quadrant) using the O-PDM. The two readings were recorded into an Excel™ spreadsheet. Next, using the control quadrant, two readings were taken lancing the subject with an Accu-Check Safe-T-Pro Plus® lancet, first using the FSL meter with a FSL test strip and then using the O-PDM with a second FSL test strip. These next two readings were recorded into Excel™. The third quadrant with scented lotion was then evaluated using the same design. The subject was lanced with the Accu-Check Safe-T Pro Plus® lancet and glucose readings were taken by first using the FSL meter with a FSL test strip and a second reading was evaluated using the O-PDM with a second FSL test strip. The two readings were then recorded into the spreadsheet. The subject was then cleaned at each quadrant using a new alcohol swab for each quadrant (for a total of 3 alcohol swabs), and allowed to dry for the next set of readings. The investigator used a new set of gloves for the alcohol cleaned quadrant readings to avoid potential cross-contamination. Using the top/first quadrant that originally had absorbed unscented lotion, the investigator took a second lance at a new site within the first quadrant using the lancet and took two readings, first using the FSL meter with the FSL test strip and a second reading using the O-PDM with the FSL test strip. These readings were recorded in the proper column of the Excel™ spreadsheet. Next, using the control quadrant of the subject, the investigator pricked a second time at a new site within the second quadrant. Using first the FSL meter with a FSL test strip, a glucose reading was measured. A second reading was measured using the O-PDM with a FSL test strip and the readings
were recorded in the spreadsheet. Lastly, the bottom, scented quadrant was evaluated. The investigator took a second lance at a new site within quadrant three. Glucose readings were then taken first with the FSL meter with a FSL test strip, and second with the O-PDM with a FSL test strip. The readings were then recorded in the spreadsheet. At the end of each participant’s time, a total of six lances and twelve readings were taken. The investigator discarded the test strips, gloves, and lancets into the proper trash and biohazard receptacles.
OBSERVATIONS

Throughout the study, consistent observations were noted. As blood samples were taken using the lancets, the ease of measurement varied. It was recorded that the scented and unscented lotions were harder to obtain a reading from the test strips compared to the control quadrant. Both areas with lotion required more blood needed per strip than the control quadrants that were able to register a reading with a smaller amount of blood. In particular, the scented lotion quadrant visually required more blood volume than the other two test quadrants. In addition, the scented lotion quadrant/lower level quadrant had the most difficult time registering with the meters when blood samples were taken. A general trend of a smaller amount of blood closer to the wrist area was consistent. Also, multiple test strips would be utilized since the scented lotion seemed to have a greater interference. In addition, once the participant was swabbed with alcohol and the second round of readings were taken, the investigator was able to take blood samples with a smaller amount of blood and readings were easier to measure with both of the meters. Participants with a greater amount of body hair on their forearms seemed to be especially difficult in regards to collecting readings, especially with the quadrants containing lotions. A general trend that occurred with each measurement was that the FSL meter was able to register a smaller amount of blood than the O-PDM. This was especially true when the scented and unscented lotions were taken into account.
RESULTS

Population Differences between Males and Females in O-PDM and FSL meter (*all mean values are reported in mg/dl)

Using the software, GraphPad®, the collected data were transferred from an Excel™ spreadsheet to the GraphPad® document. To determine if there was a gender difference in relation to the results, the control groups of both males and females were analyzed. ANOVA was used in the control groups for the unscented lotion and the scented lotion data. A two-way ANOVA was used to analyze the control groups of males and females with unscented lotion cleaned with alcohol and scented lotion cleaned with alcohol. This process was required to determine if males and females could be used as one control and an internal check between genders was determined. Using a Q-test to identify and reject outliers within the control female group, a comparison between the control data of females was analyzed by comparing the FSL meter and O-PDM data. The participant 93 years of age was excluded and considered an outlier. The FSL meter data had a mean glucose of 84.4 ± 3.3 and the O-PDM data had a mean glucose of 81.3 ± 3.0. By running a t-test with the two groups and using a two-tailed analysis, a p-value of 0.5 was obtained, and thus insignificant because the p-value >0.05.

Next, a comparison was made between the males in the control groups and the FSL meter and O-PDM data was compared. The mean for the control group of males using the FSL meter was 86 ± 5.6 and the mean for the O-PDM values was 83.5 ± 4.0. A p-value of 0.7 was determined from a t-test using the two groups and a two-tailed analysis, and thus concluded to be insignificant since was p>0.05.
Then, the female group using the control FSL meter data was compared against the male group using the control FSL meter data. Between these two groups, a p-value of 0.8 was determined and deemed insignificant (p>0.05). Lastly, for the internal check between males and females, the female group using the control O-PDM data was compared with the male group using the control O-PDM data and a p-value of 0.7 was concluded; thus being significant since p-value=0.7 > 0.05 Due to the four p-values gathered being greater than a p-value of 0.05, the difference in the data collected between males and females was insignificant, and thus I was able to compare my data with a sample size of 20 participants, instead of 10 males and 10 females.

Therefore, it can be concluded that both the O-PDM and FSL meter, are accurate compared to one another. The data reported from here on out can now be compared to the control group which consists of a population sample of 20, rather than 10 males, and 10 females, since there are no gender differences related to the control results. There is no difference between females within the O-PDM and FSL meter and there is no difference between the males using the O-PDM and FSL meter. In addition, there is no significant difference in the male data versus female data and the two groups can now be viewed as one control group. This is illustrated in Figure 1: FSL meter and O-PDM Female and Male Controls.
Confounding Factors Affecting Accuracy and Precision in O-PDM and FSL meter—Unscented and Scented Lotion Residue

Using Curel® unscented (fragrance free) lotion and Curel® scented lotion, an analysis was made evaluating a difference in blood glucose readings between the two groups by testing with the O-PDM and FSL meter utilizing FSL test strips. A difference may or may not affect clinical treatments when patients assess their glucose levels. Using GraphPad®, the data between the unscented and scented lotions were analyzed. The FSL meter control group had a mean value of 82.89 ± 2.351. These values include a population sample of n=18, since two participants were considered outliers and not included when running these tests (the two participants were noted to have elevated blood glucose levels considered “abnormal” to the study due to consumption of sugar substances immediately before testing). The FSL meter unscented lotion had a mean value of 70.33 ± 3.186. The FSL meter scented lotion had a mean of 73.56 ± 3.522. The FSL meter scented and unscented values decreased when compared to the control group of FSL meter values; the general trend can be seen in Figure 2: FSL meter: Control, Unscented, and Scented. The FSL meter unscented lotion had the greatest difference when compared to the FSL meter control group. The FSL meter unscented lotion is a significant value when compared against the FSL meter control data with a p-value less than 0.05.

The O-PDM control group had a mean value of 80.61 ± 1.861. The O-PDM unscented group had a mean value of 71.44 ± 3.080. The O-PDM scented group had a mean of 73.00 ± 2.581. Both of the lotion residues within the O-PDM group, scented and unscented, had mean values lower than the O-PDM control data. The O-PDM unscented
group had the greatest difference in comparison to the control O-PDM group and had a p-value less than 0.05, and thus, is significant. This is illustrated in Figure 3: O-PDM: Control, Unscented, and Scented.

When comparing the O-PDM values with the FSL meter values, a general trend is noted. As seen Figure 2 (FSL meter: Control, Unscented, and Scented) and Figure 3 (O-PDM: Control, Unscented, and Scented), the FSL meter control and O-PDM control have means very similar to one another. The FSL meter unscented group and the O-PDM unscented group have an identical trend and similar bar graph values (and thus heights) when compared to their control groups; both of these meters when tested with scented lotion express significant differences when compared to their respective controls. In addition, the same trend is noted when looking at the FSL meter and O-PDM groups for the scented lotions. Both of these groups have equivalent bar graphs/values and the same trends when compared against their controls; the values for these two groups is > p=0.05, and therefore is an important statistical value, but not significant. The unscented values for the FSL meter and O-PDM are much lower than their control groups and slightly lower than their scented groups.

Therefore, there is a difference between the control groups when compared to the scented and unscented groups. The differences are seen within the FSL meter (scented, unscented, and control groups) as well as the O-PDM (scented, unscented, and control groups) and the general trend is the same when comparing the FSL meter to the O-PDM. Because there is a change with and within the groups, changes from a clinical perspective may or may not be noted.
Confounding Factors Affecting Accuracy and Precision in O-PDM and FSL meter—Alcohol

After collecting data with the scented and unscented lotion residues, the quadrants were prepared with alcohol swabs and the testing sites were evaluated a second time. Using GraphPad® software, utilizing a paired t-test, the FSL meter values of alcohol were evaluated. These values include a population sample of n=18, since two participants were considered outliers and not included when running these tests. The FSL meter control group originally had a mean of 82.89 ± 2.351. Once the control quadrant was cleaned with alcohol, the FSL meter control (with alcohol) had a mean value of 82.89 ± 3.036. There is essentially no difference between the FSL meter control and the FSL meter control + alcohol group. This is illustrated in Figure 4: FSL meter Control vs. FSL meter Control with Alcohol and O-PDM Control vs. O-PDM Control with Alcohol.

The FSL meter unscented lotion group had a previous mean of 70.33 ± 3.186 before residue removal. Once the unscented lotion residue was removed with alcohol, a mean blood glucose value was 80.89 ± 2.969. There was a statistically significant difference (p<0.05) between the FSL meter unscented and the FSL meter control groups (both the control and control + alcohol) and a statistically significant difference (p<0.05) between the FSL meter unscented and FSL meter unscented + alcohol groups.

In addition, the blood glucose measurements from the FSL meter scented lotion before residue removal with alcohol had a mean value of 73.56 ± 3.522. The mean of the FSL meter scented with alcohol was 84.05 ± 2.603. There is a statistically significant difference (p<0.05) between the FSL meter scented and the FSL meter scented + alcohol.
Therefore, there are similar trends seen within the unscented and scented groups of the FSL meter in addition to similar trends once alcohol is factored in. The results for all FSL meter groups are illustrated in Figure 5: Comparison of FSL meter with Lotions versus Alcohol.

In addition, the O-PDM groups were evaluated using GraphPad® and by running paired t-tests for the data. The O-PDM control group before removal with alcohol had a mean of 80.61 ± 1.861. After the additional of alcohol, the OmniPod + alcohol control group had a mean of 81.61 ± 2.456. Therefore, there is essentially no difference (1 mg/dl) between the two O-PDM control groups. This is illustrated in Figure 4: FSL meter Control vs. FSL meter Control with Alcohol and O-PDM Control vs. O-PDM Control with Alcohol.

The O-PDM unscented lotion group had a previous mean of 71.44 ± 3.080 before alcohol was factored into the scenario. Once the lotion residue was removed with alcohol, the O-PDM scented + alcohol had a mean of 77.17 ± 2.614. There was a statistically significant difference between the O-PDM unscented group and the O-PDM control groups (both control and control + alcohol) and a p-value less than 0.05 was noted. There was a difference of 5.73 the O-PDM unscented group and the O-PDM unscented + alcohol group, however this difference was not statistically significant.

The O-PDM scented group before lotion removal had a mean value of 73.00 ± 2.581. The O-PDM scented + alcohol group had a mean of 80.42 ± 3.314. There was a difference between the O-PDM scented group when compared to the O-PDM scented + alcohol groups, and a p-value of 0.07 was determined.
Therefore, there are similar trends seen within the unscented and scented groups of the O-PDM in addition to similar trends once alcohol is factored in. The results for all O-PDM groups are illustrated in Figure 6: Comparison of O-PDM with Lotions versus Alcohol.
DISCUSSION

Tight glycemic control and maintenance of diabetes mellitus plays a vital role in patient health care. Today, health care professionals use alcohol as a cleaning agent before testing glucose levels of patients with diabetes or patients at risk for potential diabetes. The importance of proper technique of glucose monitoring is seen in this study. By first evaluating whether or not lotion residue affected glucose readings, and then evaluating if these readings were changed with removal of lotion particles with alcohol, it was determined whether or not glucose readings differed. A change was certainly seen in all patient situations. In the FSL meter groups, changes were noted in glucose readings when both scented and unscented lotions were applied to the testing sites. Both of the lotion residues, scented and unscented, were associated with a decrease in blood glucose readings observed by both O-PDM and FSL meter. There was a statistically significant decrease in glucose readings in the unscented lotion groups. It is important to note that a statistically significant difference within the scented lotion group may be obtained if there was a larger sample size.

Similar results were found utilizing the O-PDM. There was a decrease in blood glucose values between the control group and the areas treated with scented and unscented lotion. The readings from the scented and unscented lotion resulted in the values to be lower than the O-PDM control group. Similar to the FSL meter unscented group, the O-PDM unscented group showed a significant difference when compared to its control. The scented group did have a lower mean glucose value, although not statistically significant, with more participants in the same age group, a statistically significant difference may be found.
This study also analyzed the changes in precision and accuracy between meters when confounding factors were introduced into patient situations. There is accuracy that is present within the control groups of meters, both O-PDM and FSL meter. However, the precision of readings is skewed when comparing the lotion residue to the removed lotion with alcohol. Therefore, changes in precision and accuracy are introduced when confounding factors are present. The main topic in question was whether or not cleaning lotion residues with alcohol before a glucose reading affected the results. In both the FSL meter and O-PDM groups, a change was noted when alcohol was used. In the FSL meter group, there was a significant difference between the FSL meter unscented when compared to the FSL meter unscented with alcohol. The glucose readings of the FSL meter unscented with alcohol increased to essentially the same values as the FreeStyle controls. Unscented lotion is altering the glucose readings in some way and can affect the precision and accuracy of actual blood glucose readings; what is causing the unscented lotion to have such a decrease in readings is currently unidentified. In addition, the FSL meter scented with alcohol resulted in a statistically significant difference and a tremendous increase in glucose readings when compared to the FSL meter with scented lotion. The FSL meter scented lotion with alcohol spiked back up to where the FreeStyle control group values were. This general trend was also seen when comparing O-PDM values with O-PDM values of alcohol. Due to the small sample of participants, there was not a significant value seen with respect to the alcohol groups. However, a change was noted, and values seem to increase when lotion was removed from the testing sites.
It is encouraged that all health care professionals and health care teams use alcohol and/or soap and water before taking glucose readings. From this study, it can be concluded that a change in readings is certainly seen when lotion is added to testing sites. This lotion can be either scented or unscented, however, a change will result. Values were closer to control values once the lotion was removed with alcohol, thus stressing the importance of proper techniques in regards to diabetes care. This study analyzed the precision and accuracy between the O-PDM and FSL meter; however, it can be inferred that these trends would be seen in other glucose meters and test strips as well. This, however, was beyond the scope of this study.

Patients affected with diabetes can control their health through SMBG with meters and test strips. SMBG is an integral part of diabetes care. This study stresses the importance that patients must be educated in proper diabetes management. Patients more times than none will perform SMBG before even washing their hands. When glycemic control is key, it is vital to inform patients of possible confounding factors that may be present that could alter readings. The main point in SMBG is to be able to keep glucose levels in an appropriate range and when patients test sites that may contain food, lotions, dirt, etc. errors in blood glucose may result. With proper SMBG, patients are able to individualize blood glucose profiles, maintain proper day-to-day treatment options, control hyperglycemia and hypoglycemia, and enhance patient empowerment. Patients affected with diabetes can improve metabolic control and ultimately decrease the chance of secondary complications that are often fatal to a patient’s health. Patient factors have always been a problem in SMBG. Today, meters are more accurate than years in the past, and only a small volume of blood is needed to take a glucose measurement. With
this tight accuracy and precision provided by the meters, the potential for patient and confounding factors is increased since the meter may pick up the smallest trace of particles. By understanding potential sources of error, health care professionals, as well as patients may utilize SMBG more effectively. The results verify the importance of hand washing as well as cleaning testing sites with alcohol before readings in hopes that both patients and health care professionals may identify common errors and work towards education and ultimately greater diabetes care.
FIGURES

*Forearm blood glucose values are reported as mean values

FIGURE 1: FSL meter and O-PDM Female and Male Controls
FIGURE 2: FSL meter: Control, Unscented, and Scented
FIGURE 3: O-PDM: Control, Unscented, and Scented
FIGURE 4: FSL meter Control vs. FSL meter Control with Alcohol and O-PDM Control vs. O-PDM Control with Alcohol
FIGURE 5: Comparison of FSL meter with Lotions versus Alcohol

*=FSL meter Unscented is statistically significant (p<0.05) to FSL meter Control and FSL meter Control + Alcohol

T=FSL meter Unscented + alcohol is statistically significant (p<0.05) when compared to FSL meter Unscented

#=Alcohol + FSL scented in statistically significant (p<0.05) when compared to FSL scented
FIGURE 6: Comparison of O-PDM with Lotions versus Alcohol

* = O-PDM Unscented is statistically significant (p<0.05) when compared to O-PDM Control and O-PDM Control + Alcohol

p=0.07 Alcohol + O-PDM scented when compared to O-PDM scented
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