F-Scan Analysis of Prosthetic Fittings through Mercer on Mission Vietnam

Emily Brett[1] Matthew Yin[2] Ha Van Vo[3] Edward O'Brien[4] Loren Sumner[5] Philip McCreanor[6]

Abstract – Mercer on Mission Vietnam is an annual service learning course which students spend time fitting prosthetic limbs on amputees. The prosthetic utilized in these trips includes a universal socket designed at Mercer University. The design is a low cost prosthesis that accommodates as many impoverished amputees as possible. During the summer of 2013, 18 students and 3 professors fitted 272 amputees. Fifty-three sets of Tekscan F-Scan Plantar Pressure data were collected. Students analyzed the plantar pressure data and tested for statistical trends between age, weight, height, amputation date, and gender to seek trends that could lead to improvements for the next trip. None of the five factors tested correlated with the quality of prosthetic fit. It was determined that a more systematic method of F-Scan data collection was needed in order to increase consistency and sample size for more in depth trend analysis.

Keywords: F-Scan, Analysis, prosthetic, trends, gait

INTRODUCTION

Since 2009, Mercer University has fitted amputees with a low cost universal prosthetic in Vietnam during the summer. The program is named Mercer on Mission Vietnam and improvements on the prosthetic design and fitting process are made each year. Each new improvement leads to faster fittings, stronger prosthetic designs, and more efficient instruction on how to fit prosthetics. In the summer of 2009, Mercer on Mission fit 27 amputees with prosthetics; come the summer of 2013 four years later, the team was able to fit 272 prosthetics. In total, over 450 amputees have been fit through Mercer on Mission Vietnam. Over the five years the program has been active, an enormous amount of growth in efficiency has occurred. This is due to an ever improving design/fitting process.

In the past, improvements were made based off of observation from team members. Each trip to Vietnam was followed by reflection. How successful was this year's trip? What were some positive improvements that were implemented to make the trip more successful? What was an area of weakness that the team had? What can we do to make next year's trip even more successful? The team members all asked themselves these questions and more at the completion of each trip. Reflection can only go so far though; how can the team continue to improve and evolve over time despite the numerous improvements already made? Often time areas that can be improved are overlooked because they are not as easy to isolate. Is the Mercer on Mission Vietnam team more proficient at fitting a certain

[1]Biomedical Engineering Student, 1400 Coleman Ave. MU Box 71058 Macon, GA 31207, Emily.J.Brett@live.mercer.edu

[2]Biomedical Engineering Student, 1400 Coleman Ave. MU Box 71285 Macon, GA 31207, matthewmuong@gmail.com

[3]Associate Professor, Department of Biomedical Engineering, Mercer University, 1400 Coleman Avenue, Macon, GA, jenkins_he@mercer.edu

[4] Professor, Chair, Department of Biomedical Engineering, Mercer University, 1400 Coleman Avenue, Macon, GA, jenkins_he@mercer.edu

[5] Professor, Chair, Department of Biomedical Engineering, Mercer University, 1400 Coleman Avenue, Macon, GA, jenkins_he@mercer.edu

[6] Associate Professor, Director of Engineering Honors, Department of Environmental Engineering,, Mercer University, 1400 Coleman Avenue, Macon, GA, jenkins_he@mercer.edu

type of amputee? Is the prosthetic design not performing as well for a certain age group or gender? Does the design's performance suffer as the weight of the amputee increases?

These are all questions that cannot be answered solely through observation and reflection after each trip. Visualization of these longer term trends can be accomplished through a more quantitative approach towards reflection. The purpose of this paper is to determine if F-Scan data collected through the 2013 Mercer on Mission Vietnam trip can be used to identify areas that have room for improvement. The hope is that through data analysis, statistical trends will surface revealing areas that can enhance the success of the Mercer on Mission Vietnam program even further.

F-Scan Data

F-Scan is a system from the company Tekscan that uses thin sensors placed inside a person's shoe to record the pressure that their foot exerts as they walk and the distribution of this pressure [1]. The system helps reveal information about the interaction between the foot and footwear, Figure 1. The F-Scan software allows force, timing, and contact pressure distribution to be measured through the in-shoe plantar pressure mapping system. Accurate data can be collected using the high-resolution sensors from F-Scan that fit seamlessly into a shoe. The sensors have white lines that can be trimmed to accommodate variations in shoe size during testing. The entire F-Scan system is portable to allow for mobile data collection.

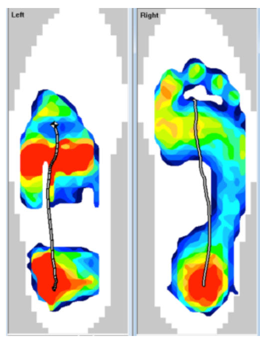

Figure 1. Example of the results from an F-Scan trial run

Gait Analysis

Under the analysis of a prosthetic fitter, F-Scan can be quickly utilized to effectively conclude whether or not a prosthetic is properly fit. This requires a basic understanding of the human gait cycle and the reaction forces on the foot during walking. There are two stages of the human gait cycle: the swing and stance phase, Figure 2. In the swing phase, the foot being analyzed undergoes zero forces because it is being propelled through the air in preparation for the next phase: the stance phase.[3] The stance phase begins with the heel striking the ground; as the heel strikes, all of the force from the foot accelerating through the air gets dissipated and sent up through the rest of the body. The initial heel strike is where the F-Scan should show a peak in force. Then the foot shifts the weight forward and the forces shift and spread throughout the foot as the mid-stance occurs. As the weight shifts towards the metatarsals, the gait cycle now approaches toe off. Toe off is another point in the cycle where the F-Scan should show a peak in force. This is where the body pushes off at the toes and propels the leg back into the swing phase of the gait cycle. A natural gait can be easily shown through F-Scan. All of the features discussed above should be present in analysis and the forces applied should be present in equal magnitude and duration between the two feet.

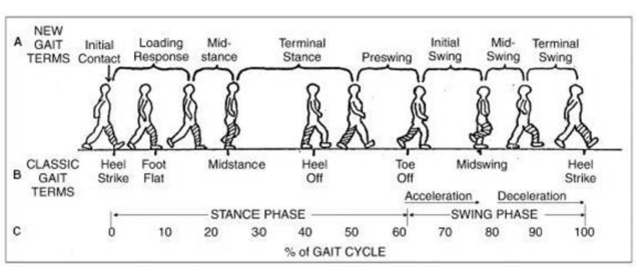

Figure 2. The gait cycle [2]

Objective

The Mercer on Mission-Vietnam trip has utilized Tekscan's F-Scan in shoe analysis system to collect amputee gait data since 2011. The F-Scan system collects pressure data from patients while they walk. In a typical clinical setting this data is used to optimize the device for each patient. For Mercer on Mission, the F-scan system is vital for collecting data that can be used for research and development when the students return to the United States. Because they live in remote areas, the amputees that Mercer on Mission fits will not likely ever see the team again after being fit. This makes it even more important to collect data right after fitting for later analysis because there is only one opportunity to collect data.

In the last three years, Mercer on Mission Vietnam has made it a goal to improve data collection for gait analysis. For the 2011 trip, 30 sets of F-Scan data were taken out of 75 amputees fit. In 2012, the team collected about 50 sets of F-Scan data out of the 206 amputees fit. In 2013, around 150 sets of data were taken through the F-Scan system. More details on how F-Scan was used on Mercer on Mission will be discussed in the Methodology section.

The goal of this research was to organize F-Scan data collected thus far. Once organized, the F-Scan data would then be analyzed and noted in a standard method for easy future reference. After analysis, the main objective was looking for trends in the data that would help pinpoint areas of improvement for future Mercer on Mission Vietnam trips.

METHODOLOGY

The following section describes the process of how data was collected by the Mercer on Mission Vietnam Program. Two types of data were collected: medical information and F-Scan data. The F-Scan data was used to quantify the quality of a prosthetic fit and medical data was utilized in formulating trends or relationships between quality of fit and relevant patient factors.

Data Collection

Every amputee that comes to Mercer on Mission Vietnam must go through check in. During check in, relevant medical information is collected; every patient had to fill out a patient information sheet. This paperwork recorded details about every person fit with a prosthetic or treated in clinic by the Mercer on Mission program. Basic information was collected for each patient such as name, age, gender, height, and weight. Medical history, current illnesses, blood pressure, and pulse were amongst the medical records that were important for fitters to know before working with any patients.

Then a prosthetics team will be assigned to fit the amputee with a prosthetic. First, the patient's range of motion (ROM) and muscle strength were measured. Then, the length, proximal circumference, medial circumference, and distal circumference of the residual limb were measured as this information helps with further organization of the various types of amputations. Once the prosthetic was fit and approved by a certified prosthetist or orthopedic surgeon present, the F-scan system was equipped, Figure 3.

Figure 3. Two Mercer on Mission Vietnam team members setting up a patient for F-Scan

F-Scan pressure data was then collected for the patient. Using the weight data collected above, the F-Scan was calibrated to each patient's weight. Two sets of eight second F-Scan data was collected for each patient. Video recording of each patient's walk was also taken; as a backup source of gait analysis data. All of this information collected for each patient via paper forms was transferred to Excel for analysis.

Data Organization

Once the team returned from Mercer on Mission Vietnam, the next step was to sift through all of the data collected and to begin organizing all of it in order to streamline the analysis process. This was done on Microsoft Excel; each row is reserved for the medical information and analysis results for an individual patient, Table 1.

Table 1. Example of the Data contained in an Excel Spreadsheet**.**

Patient Code	Gender	Age	Height (cm)	Weight (kg)	Years as Amputee	Amputee Classification
1	Female	47.00	149.00	50.00	30.00	BKL
2	Female	55.00	164.00	58.00	42.00	BKL
3	Female	82.00	152.00	27.00	45.00	BKL
4	Female	20.00	106.00	39.00	14.00	BKR

As data was filtered, many issues arose before analysis could begin. For instance, due to the large number of patients that were fitted, and the small staff that filed the paperwork, much of the medical information was filed incorrectly or lost. This rendered some of the F-Scan data unusable in this trend analysis research. While reviewing the collected F-Scan data, it was discovered that over half of the data that was collected could not be used because of calibration errors and/or software errors that are still being resolved at this time. Also adding to the amount of unusable information was that F-Scan data was not collected for some patients due to time constraints as well as hardware issues that arose while overseas. In the end, 250 patients had medical data and roughly 150 F-Scan pressure data was collected out of the 272 patients that were fit last summer. With incorrectly calibrated data and F-Scan data that could not be opened because of Tekscan software issues, this 150 was reduced to only 53 usable sets of F-Scan data out of the 272 patients fit last trip.

F-Scan Analysis

Analysis was completed through graph analysis in Tekscan's F-Scan software. Two graphs are most effective for determining a proper fit with F-scan analysis. The first is a Force vs. Time graph, Figure 4. In this type of graph, the y-axis is the force applied (kilograms) and the x-axis represents time (seconds). There are two sets of data represented on each graph: one for the force applied on the left foot, and one representing the force applied to the right foot. Each foot is denoted by either green (right foot) or red (left foot). In the Force vs. Time graph, the swing phase discrepancies were calculated. Swing phases are characteristically defined as the time that each foot has no force shown on the sensor. Because the foot is swinging through the air as opposed to contacting the ground, 0 kg of force occurs in this phase.

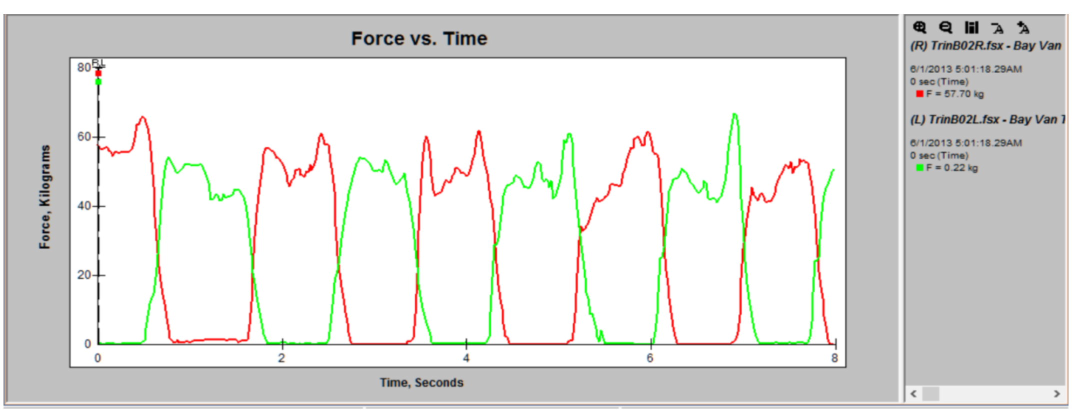

Figure 4. Force vs. Time Graph for F-Scan Analysis

In a properly fit prosthetic, the swing phases between both legs are equal. Total stride time is the amount of time it takes for one foot to go from stance phase to swing phase and back to the beginning of the next stance phase again. For analysis, a percent swing phase difference was used. By taking into account the total stride time of a patient, this ensures that analysis stays consistent between patients with differing gait speeds. In order to calculate the percent swing phase, the equation below was used:

$$Percent\ Swing\ Phase\ difference = \frac{|T(left) - T(right)|}{Ttotal}$$

$$T(left) = Time\ of swing\ phase\ of\ left\ foot$$

$$T(right) = Time\ of swing\ phase\ of\ right\ foot$$

$$Ttotal = Time\ of\ Total\ Stride\ Length$$

The second type of graph, the Force vs. Percentage graph, effectively outlines how the weight is distributed across the foot, Figure 5. The y-axis represents the average force applied while the x-axis divides the foot length into specified percentages; 0% represents the heel of the foot and 100% represents the toes.

Figure 5. Collected plantar pressure data divided into percentages for a Force vs Percentage graph

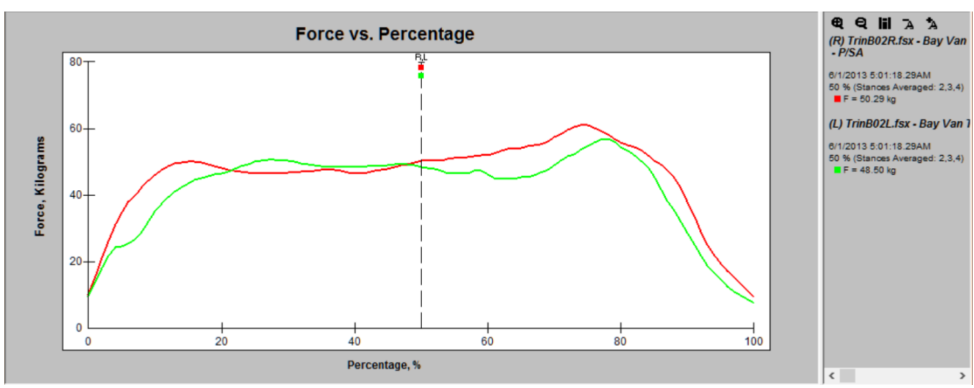

Figure 6. Force vs. Percentage Graph

The Force vs. Percentage graph qualitatively displays a symmetrical distribution of forces amongst both feet, which gives evidence of a smooth, natural gait. Quantitatively however, finding the average force on each foot can help in defining a biomechanically sound gait. The force differences between the two feet were estimated using the percent difference of average force between the two legs was calculated. By using the percent difference as opposed to absolute, analysis is standard between patients with different weights. The following equation describes the percent difference of force:

$$Force\ Percent\ Difference = \frac{|F(left) - F(right)|}{Body\ Weight}$$

$$F(left) = Average\ Force\ on\ Left\ Foot$$

$$F(right) = Average\ Force\ on\ Right\ Foot$$

Quality of Fit Rating System

F-Scan analysis as outlined above was done for each of the patients. Columns for both the Force Analysis Rating and Swing Phase Analysis rating were added in the Excel files. The next step in streamlining data for more efficient data analysis was scaling the Force Analysis and Swing Phase Percentage differences into a universal scale; the scale selected had six levels, Table 2. A score of six represents the lowest percent difference which correlates to the best prosthetic fits and most natural gaits. A graphical representation of the scale used is shown below: X represents the percent difference for either swing phase or average force. A score of six indicates an excellent fit while a score of one indicates problems with the prosthetic fit.

Table 2. Scale for Percentage Differences

6	X<5%
5	5%<X<10%
4	10%<X<15%
3	15%<X<20%
2	20%<X<25%
1	X>25%

Trend Analysis

After rating each individual fitting, the next step was to find correlations between the quality of fit and various factors. The factors that were tested include: age, height, weight, time as amputee, gender, and handedness. For age, height, weight, and time as amputee factors, the quality of fit rating and independent factors were graphed. The quality of fit ran along the y-axis and the x-axis is defined by the independent factors. Through regression analysis, a determination could be made in regards to how much of an impact each factor seemed to make on the quality of fit. For the gender and right vs. left leg factors, a two sample t-test was conducted to test whether or not there was a difference in quality of fit between male and females, or whether there was a difference between right and left leg.

RESULTS AND DISCUSSION

The following section displays the results from F-Scan Analysis. Each factor has a table or figure and brief paragraph explaining the significance of the factor on the quality of fitting. Five factors: time as amputee, weight, height, age, and BMI were analyzed through excel graphs to determine correlations. Results from comparing gender and leg amputated are shown below in tables displaying the results from a t-test between two samples assuming equal variances.

In Figure 7, the y-axis represents the fitting rating and the x-axis outlines the amount of time the patient has been as an amputee. When patients checked into the clinic, they were asked for the date of their amputation. This graph shows that there is not much correlation between the fitting rating and time as amputee, or the time since the patient's amputation occurred. The regression analysis shows 2%, which supports no correlation. It was expected that patients that have been amputees for a longer amount of time would have better ratings for their prosthetic fits. Patients that have been amputated longer will have had time to adjust to a new center of gravity as well as increase their chance of already having a prosthetic. If a patient already has had a prosthetic, then he/she will have a better idea of what kind of prosthetic they can walk with most naturally. Those patients will have better input when the students fitting them ask for preferences concerning how they want their prosthetic to fit.

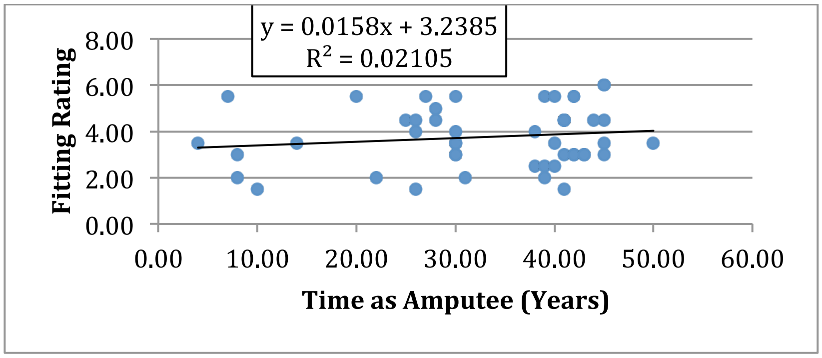

Figure 7. Rating of Fitting vs. Time as Amputees

Figure 8 presents the relationship between fitting rating and the weight of the patient. Each patient was weighed during check in at the prosthetics clinic. Similar to the time as amputee graph, there is not much evidence to support a correlation with fitting rating. Roughly 2% on the regression analysis is not enough to make a clear conclusion. It was hypothesized that those within a certain weight range would have the best fits. A patient that is too heavy would have more trouble walking with the prosthetic because it is specifically designed for weights under 70 kg. At weights much greater than that, the prosthetic may not be as supportive. A patient that is too light however, may not have the muscle mass needed to move around in a prosthetic. Therefore it was hypothesized that a patient between 40 kg and 70 kg would, on average, have the better prosthetic fit.

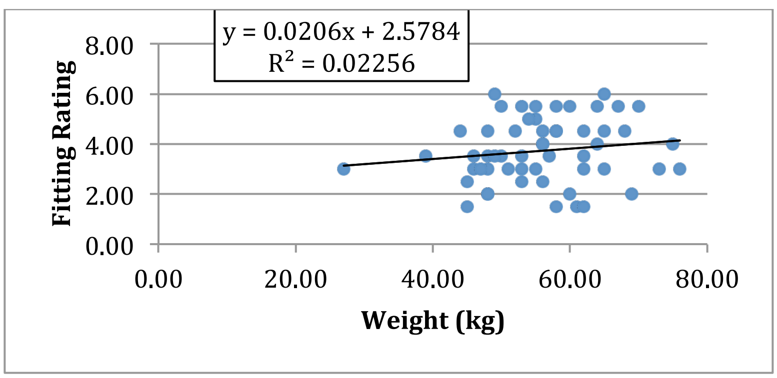

Figure 8. Fitting Rating vs. Weight

In the Fitting Rating vs. Height analysis, Figure 9, there was even less evidence of correlation; regression analysis yielded 0%. This is a clear indicator that the height of the patient does not negatively affect the quality of fitting. It was hypothesized that height would not play as much of an impact on prosthetic fit, unless the patient was unusually short/tall. The prosthetic is designed to support a wide range of heights and therefore differing heights should not make much of an impact at all. This would be especially true in below the knee amputation patients, which is a majority of patients that were fit.

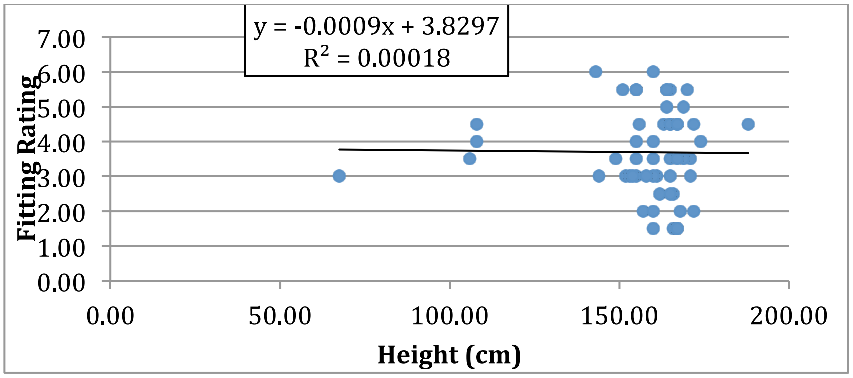

Figure 9. Fitting Rating vs. Height

In the Fitting Rating vs. Age analysis, Figure 10, no evidence of correlation could be determined; regression analysis yielded 0%. People aged 15-60 years old were hypothesized to have better fits. This hypothesis was made because amputees older than 60 would have joint and muscular problems that could negatively affect the patient's ability to walk on the prosthetic. If an amputee is below 15, it can be inferred that they are still growing and may still be getting used to their body. This is true for any normal child of that age, and is a much bigger problem in amputees because they have to adjust to a different center of gravity on top of a fast rate of growth and change.

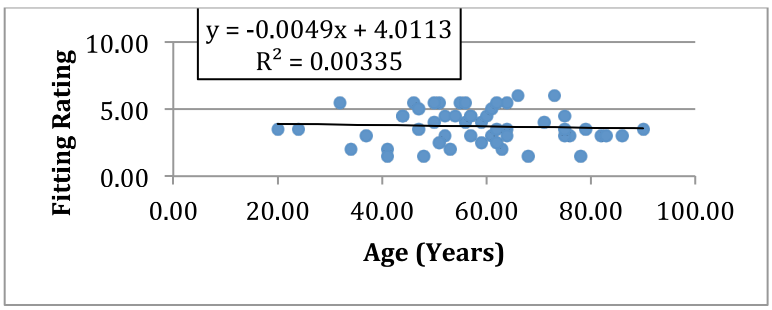

Figure 10. Fitting Rating vs. Age

Figure 11 presents the relationship between fitting rating and the body mass index (BMI) of the patient. Each patient's weight and height were recorded during check in at the prosthetics clinic. The equation for calculating BMI is as follows:

$$BMI = \frac{Weight}{Height^2} = \frac{kg}{m^2}$$

There are four categories for distinguishing BMI in people using body weight and height values. The first range is any BMI score less than 18.5, for underweight people. The healthy normal range for body mass index is between 18.5 and 24.9. Values between 25 and 29.9 fall into the overweight weight range. The last weight range is any value over 30, which refers to obese people. Similar to the time as amputee graph, there is not much evidence to support a correlation with fitting rating. Roughly 2% on the regression analysis is not enough to make a clear conclusion. It was hypothesized that those within the normal BMI range would have the best fits.

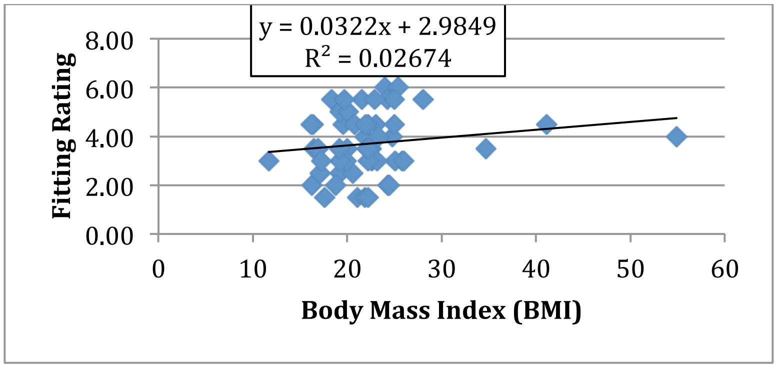

Figure 11. Fitting Rating vs. BMI

Table 3 presents the findings from the t-test analysis between patients that have been amputated on the left and the right limbs. The t-test between below the knee amputation patients with either their right or left legs amputated, yielded a p-value of 0.06, which is beyond the 0.05 p-value that was desired for a 95% confidence interval. Therefore, it was concluded that there was no evidence supporting the idea that the mean fitting rating between right and left leg amputees are statistically different.

Table 3. Two Sample t-Test, Left vs. Right Leg Amputation

t-Test: Two-Sample Assuming Equal Variances for Left vs Right Below the Knee

	BKL	*BKR*
Mean	4.02	3.37037
Variance	1.718333	1.299858
Observations	25	27
P(T<=t) two-tail	0.061801	
t Critical two-tail	2.008559	

Despite only having data for six female patients as opposed to 49 male patients, a t-test was conducted between female and male amputees that were fitted as seen in Table 4 below. The t-test resulted in a p-value of 0.77. This provides no evidence whatsoever that the rate of fitting between male and female patients differ.

Table 4. Two Sample t-Test, Gender

t-Test: Two-Sample Assuming Equal Variances for Gender

	Female	*Male*
Mean	3.583333	3.744898
Variance	1.341667	1.667942
Observations	6	49
P(T<=t) two-tail	0.771473	
t Critical two-tail	2.005746	

Conclusion

Of the five statistical tests done for age, weight, height, time as amputee, gender, and limb side differences, none of them produced results that would suggest that the Mercer University Universal Prosthetic was better suited for any of those differences. This was with a limited sample of amputees however. Only a total of 53 patient data was cross-referenced with their F-Scan data analysis for this study. This was due to a number of limiting factors:

1) F-Scan data was not collect for all amputees that were fitted. Of the 272 patients that were fitted, only 150 sets of data were collected. Some patient data could not be collected because patients travel from long distances to get fit and some fittings can take hours to complete. Oftentimes, this means that the patient will begin getting fit around 1 pm and complete around 6 pm.; collecting proper F scan data can take another 30 to 60 minutes and oftentimes the patient cannot stay for that. Therefore a number of patients must leave without having F-Scan data taken. This issue, along with other F-Scan related issues like running out of batteries, reduced the number of samples from 272 to 150.

2) Of the 150 sets of data collected in Vietnam some of the collection was not done correctly and made analysis difficult. Issues like incorrect calibration and misaligned sensors did not allow for proper analysis of a significant amount of data. This resulted in only 80 sets of data being fit for analysis.

3) With 272 amputees to organize, and 1800 clinic patients with paper work to be organized as well, the opportunity for paper work mix ups was always present. This was on top of the fact that paper work was done in the Vietnamese language and needed to be translated for analysis. Students collecting data would sometimes mix up names and dates and this made it difficult to completely organize the patients as theoretically planned. Roughly 30 of the usable F-Scan data sets did not have a corresponding patient medical sheet that went with it. This data could not be used for trend analysis and left the study with a sample size of 53 patients.

Only having 53 sets of patient data to analyze for trends proved to be an obstacle. To properly analyze for trends, a much larger sample size was needed. In order for future trend analysis to be done properly, there needs to be a method for better organizing the hundreds and thousands of patient medical papers that are in the Mercer on Mission-Vietnam Database. Also, although F-Scan data collection has improved since it was first introduced into the program in 2011, issues with the system still limit the amount of data that can be analyzed. In the upcoming 2014 trip, it will be a priority to set up a more universal and successful method of F-Scan data collection so that the number of samples increases.

There were a number of other factors that were desired to be analyzed but there was neither proper data nor time for proper analysis of them. Some of these factors include: the number of prosthetics that the amputee has owned, the number of years the amputee has been walking in a prosthetic, the stump dimensions, and comparing fittings between prosthetic teams from year to year. If a better system of data collection was implemented, students could analyze which year's designs were more successful, whether or not changes they implemented in the prosthetic design improved fittings or made no significant impact, and address areas of weaknesses that the prosthetic design has.

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BIOGRAPHIES

Emily Brett

Emily Brett is a Senior Biomedical Engineering student at Mercer University. Currently, she is pursuing a Bachelors and Masters of Science in Biomedical Engineering. She have been involved in research with Mercer on Mission-Vietnam and the F-Scan data She was part of the Summer and Winter 2012 Mercer on Mission Teams.

Matthew Yin

Matthew Yin is a Senior Biomedical Engineering student at Mercer University. He is currently working towards his Bachelors and Masters of Sciences in Biomedical Engineering. He is also currently involved with research with Mercer on Mission Vietnam and Senior Design. He went on Mercer on Mission Vietnam the Summer and Winter of 2012 as well as the Summer of 2013.

Dr. Ha Van Vo

Dr. Ha Van is a Biomedical Engineering professor at Mercer University. He is the engineer behind the Universal Socket Design that Mercer on Mission Vietnam fits. Dr. Vo is an orthopedic surgeon, and started start of the Mercer on Mission Vietnam Program in 2009. He still continues to lead research and improvement on the prosthetic design.

Dr. Edward O'Brien

Dr. Edward O'Brien is a Biomedical Engineering professor and Program Director of the Biomedical Engineering Department at Mercer University. He has been a part of the Mercer on Mission Program since 2010, and just took his last trip to Vietnam in the summer of 2013. In his three years with the program, he made sure to instill into students the motto: build a little, test a little.

Dr. Loren Sumner

Dr. Loren Sumner is a Mechanical Engineering professor at Mercer University. He became part of the Mercer on Mission team in the summer of 2013 and plans to return for Mercer on Mission Vietnam 2014.

Dr. Philip Mccreanor

Dr. Mccreanor **holds a B.S. in Mechanical Engineering M.S. in Environmental Science, and a Ph.D. in Environmental Engineering. He currently holds the rank of Associate Professor in the Environmental Engineering Department and is Director of the Engineering Honors Program at Mercer University. He has been inducted into the Phi Kappa Phi, Sigma Xi, and Tau Beta Pi honor societies. His professional awards include Frontiers in Education New Faculty Fellow; Outstanding Referee by the Waste Management: Journal of Integrated Waste Management, Science, and Technology; the Mercer University / Vulcan Materials Company Innovations in Teaching Award; Georgia Governor's Teaching Fellow; and the ASEE-SE's 2012 Outstanding Mid-Career Teacher. His research interests include flow and transport in variably saturated media, bioreactor landfills, and gray water reuse.**

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