Intermachine Validity and Reliability of The F-mat and F-scan

Kim, Kyoung, P.T., M.A  
Department of Physical Therapy, Division of Health Science, Taegu University

Park, Young-Han, P.T., M.S  
Department of Physical Therapy, Chongju National College of Science & Technology

Bae, Sung-Soo, P.T., Ph.D  
Department of Physical Therapy, College of Rehabilitation Science, Taegu University

발압력 측정계(F-mat과 F-scan system)의
신뢰성과 타당성에 대한 연구

대구대학교 보건과학부 물리치료과  
김 경

국립 청주과학대학 물리치료과  
박 영 한

대구대학교 재활과학대학 물리치료학과  
배 성 수

〈국문초록 〉

본 연구의 목적은 함관(Force plate)의 지면반발력(Ground reaction force)의 비교에 따라 발압력 측정계(F-mat와 F-scan)의 상호가재가의 신뢰성과 타당성을 연구하는데 목적을 두고 있으며 정상인과 리스프랑크(Lisfranc) 골절을 가지고 있는 환자를 대상으로 본적 연구하게 되었다.

함관의 지면반발력기 기준으로 설정하고 정상인과 환자의 각각 오른발과 왼발의 스텝에 대해 F 메트(F-mat)와 F 스킨(F-scan) 시스템의 그레피 비교 모식과 시간에 따른 보행모식의 차이에 따라 이 논문에 대한 결과를 얻을 수 있었다. 본 연구에서는 F 스킨 시스템의 데이터 분석을 새로운 실현한 3.622와 아리크로 소프트웨어의 엑셀 97를 통해 세 시스템의 점의 평균치의 그레피를 통해 비교 분석하게 되었으며 다음과 같은 세가지 점화를 얻을 수 있었다. 첫째로 F 스킨의 지면 반발력은 함관과 비교하여지며 통계적으로 중요한 차이점을 얻을 수 없음을 것이다. 두번째, F 메트를 위한 지면 반발력에 함관과 비교하여지며 통계적으로 중요한 차이점을 얻을 수 없음을 것이다. 세번째로 정상군과 실험군의 지면 반발력에 대해 중요한 차이점이 있을 것이라는 것이 밝혀졌다. 특히 정상군의 대상자는 실험군의 대상자와 비교 되어질 때 각각에 대해 증가된 지면 반발력을 나타냈다.

이상 본 연구에 대해 다음의 결론을 내릴 수가 있었고 기존의 F 스킨 시스템이 임상적으로 많이 쓰여졌지만 F 스킨의 셀이에 대해 많은 이견 그 차이를 보였다. 한편, F 메트 시스템에서 F 메트 셀의 일반화에 대해서는 어느 연구 논문도 나오지 않았고 이에 대해 F 스킨(F-scan)과 함관(Force plate)을 상호 비교하여 F 메트 시스템에 대한 신뢰성과 타당성을 연구하는데 목적을 두게 되었다.
I. INTRODUCTION

Researchers and clinicians who wish to gather specific information regarding ground reaction forces during gait have a variety of instruments at their disposal which are capable of such analysis. These include the Force plate and the F-scan, both of which have been used for various patient populations to determine abnormalities in foot pressure, efficacy of orthotics, and weight bearing patterns in diabetics to name a few.

Force plate is a platform set on or into the floor that is instrumented to measure the forces imposed on it. It is able to record two steps during gait, but has the inherent problem of requiring the patients step to land directly on the plate. (Ellen, 1991) Trials that do not produce a perfect ground reaction force reading must be eliminated from the results.

The F-scan system also provides bipedal plantar pressures using a paper thin disposable sensor placed in the shoe. The F-scan sensor detects, displays, and records plantar forces between the foot and shoe while they take place without interfering with the patients’ normal gait. The sensor is worn in a shoe and as such, records the pressures obtained at the shoe/foot interface. The studies of the F-scan were done by many researchers and initial studies that examined the F-scan include Mueller et al whom examined peak plantar pressures with hip and ankle walking strategies in-patients with neuropathic ulcers. (Mueller, 1996)

They found changes in properties of the pressure sensors over time that they concluded could be reduced by using a new sensor with each subject. Rose et al examined foot pressures using insole sensors and heel wedges to measure plantar pressure distribution and center of force. Similar to Mueller, these authors found that the F-scan is reliable for measuring pressures, but limitations of the device included the need to use one insole per subject, the consistency of only 5-6 trials per sensor, and discrepancy between different sensors and variability between shoe types. (Rose and Feiwell, 1992) Woodburn also found poor durability of the sensors and a large difference between and within sensors. They concluded that the F-scan does not produce repeatable measurements. (Woodburn, 1995)

Mueller and Strube examined the generalization of the F-scan system. They found that the F-scan reliability could be improved by allowing the F-scan to adjust temperature for 10 minutes prior to use. They concluded that the manufacture guidelines might be adequate for accurate F-scan data collection, especially if correlated with a force plate and over various days and subjects. (Mueller, 1994) Most recently, Luo et al attempted to validate the F-scan pressure system. Their results agreed with those of previous authors in that the sensors are affected by the type of surface, the speed with which loading is applied, and the temperature of the sensor. Luo agreed with Mueller that calibration is necessary for accurate measurement. Finally, Luo also noted that hard surfaces result in less accurate measurements. (Luo et al, 1998)

Sumiya et al looked at the sensing stability and dynamic response of the F-scan. Their results indicate that there is no relationship between the amount of pressure and sensor sensitivity. They also note that the sensitivity was affected by the thickness of the material at the foot interface. Sumiya concluded that the F-scan results did not consistently coincide with the data obtained from the force plate. The authors recommend the use of the F-scan for relative comparisons used under constant conditions. (Sumiya, 1998)

Brown et al studied the effect of different orthosis on foot pressure distribution using the F-scan system. In this study, they were able to determine that plastic orthosis reduced forefoot peak pressures. One subject ambulated four times
for twenty trials with a new sensor for each trial. The authors found variations in peak pressure between the twenty different sensors. In spite of the variability due to the sensors, differences were detected among the tested orthosis. Other limitations of the F-scan system include: poor sensor durability secondary to the thickness of the sensor and the smooth polyester material. Also, because the sensor is flexible in two directions, it does not adapt well to curved surfaces and the upper pressure range of the sensor (1250 Kpa) is too low for use in patient populations who produce higher plantar pressures. (Brown et al. 1996)

Cavanagh also summarized his dissatisfaction with the F-scan by stating "Until problems with the calibration and stability of the F-scan insoles are solved, I would not recommend the use of the device in applications where accuracy and reliability are important." (Cavanagh, 1995) As such, many studies of F-scan were discussed and their studies indicated many different opinions in the clinical setting.

A newer device, the F-mat system is a 470mm X 320mm mat with a spatial resolution of 1.4 cells/cm2. The F-mat is designed for measuring pressures between the foot and supports surfaces and allows analysis of many strides in a gait cycle due to its length. It is easy and convenient to use in a clinical and research setting for this reason. The patient is not required to wear any special devices on his feet and this allows a more normal replication of gait. The F-mat has also been proposed to allow analysis of foot pressures. (Tekscan, Boston)

However, no literature exists on its validity and reliability. This need exists to determine if results obtained from the F-mat can be correlated to results from the F-scan. Reasons for this include the ability to compare study results obtained from both pieces of equipment, as this will allow clinicians to decide which piece of equipment is indicated for a particular analysis. Knowledge of the compatibility of the F-mat and F-scan will allow comparison of results from various studies that use these measurement devices.

Clinically, it is important to ascertain the reliability of the F-scan and F-mat as the selection of appropriate equipment and treatment techniques, in both healthy and patient populations, is based on this research. Therefore, the purpose of this study will be to determine the inter-machine validity and reliability of the F-mat and F-scan as compared to a force plate via analysis of a single subject with a Lisfranc fracture and a control subject.

II. METHODS AND MATERIALS

The subproblems of this study are to determine the validity and reliability of the F-mat as compared to the force plate and the validity and reliability of the F-scan as compared to the Force plate and the relationship between of the F-scan and F-mat in a normal and patient population. Null hypothesis of this study is that the F-scan and F-mat will not provide valid measures of foot pressure when compared to the force plate for the control and patient groups. Research hypothesis will be that the ground reaction force recordings for the force plate will show no statistically significant difference when compared with the F-scan. The ground reaction force recording for the force plate will show no statistically significant difference when compared with the F-mat. Ground reaction force recording for the control vs. test subject will show statistical significance.

Pressure measurements including ground reaction force, center of pressure, and total area will be obtained from the F-scan and F-mat and compared to a Force plate to determine their validity and reliability of these instruments. Ground reaction force will be measured using the force plate and will be used as the "Gold
standard for pressure measurement to determine reliability and validity of the F-scan and F-mat. Peak pressure and total force will also be evaluated as Hughes et al found these to be the most reliable measures when they examined factors that affect reliability of foot pressure. (Hughes, 1987)

Two female subjects will participate in the study. One subject will be a 28 years old without pathology, the other a 16year old female with a Lisfranc fracture to allow comparison of pressure distributions. The equipment utilized will include F-scan (Tekscan, Boston) which includes a pressure sensitive insole sensor, a lightweight 9-volt battery powered transducer, 9.25m coaxial cable, computer and software. Other equipment will include a stockingette, tape measure, F-mat (Tekscan, Boston) and kistler force plate. The specific parameters and additional information concerning the F-mat and force plate will be included in this proposal once further information is available from their respective manufacturers.

The F-scan will be secured to the plantar surface of the foot with a stockingette. All trials will be completed with one foot and then with the opposite foot. This method has been chosen to allow measurement of pressures at the foot-floor interface for both the F-mat and F-scan systems. Ground reaction force will be the primary dependent measure. Center of pressure and total area will be secondary dependent measures. Measures will be recorded during 6-8 steps of normal gait and each subject will walk at their own self-selected rate. One step will be recorded which lands over the force plate, all other trials will be eliminated. Each subject will perform 10 trials on each foot using the F-scan while walking along the F-mat and over the force plate. All three systems will be used on each trial and data will be recorded simultaneously for all three measuring devices.

We are testing to see if pressure readouts show statistically significant differences between the F-scan, F-mat, and force plate systems. After completing the trials, data will be collected and saved in the computer. The data collected will be analyzed to test the null and research hypothesis put forth for the purposes of this study. This study will take place in the Physical Therapy Department Human performance Laboratory at New York University.

II. RESULTS

For the data analysis of this study, new version of F-scan software, 3.622 and Micro soft Excel 97 was used. The total force values of F-scan and F-mat system were plotted against time with the vertical component of the ground reaction force measured by the force plate. The force/time curves of both devices were compared and analyzed by the time of gait analysis such as initial contact, loading response, midstance, terminal stance, preswing.

Figure 1 shows the average ground reaction force between the F-mat, F-scan system when compared to the force of force plate and right step of test subject was measured and the measured force was plotted against time from 0 to 0.7 seconds. The force values of the F-scan and F-mat yielded two-peaked curves but did not always coincide with the vertical component curves of the ground reaction force. Figure 2 also shows the force/time curves of the three systems of left step of patient subject. The force values of two systems did not produce the consistent values when compared to the ground reaction force of force plate regarding the patient subject.

Figure 3 and 4 shows the ground reaction force of two peaks over time of right and left step of control subject including only two systems (F-mat and Force plate). In viewing the ground reaction force curves, the F-mat system indicated the consistent curves and values when compared to the standard value of the force plate. However, in
detail, the F-mat system consistently showed a delay in time to reach the first maximum point (loading response), and reached the second maximum point (terminal stance) maximum before the force plate system. Also, in the data analysis of control subject, the data for the F-scan system was not collected due to the breaking of the delicate F-scan sensors when used without a shoe. Different sensors were used to record the data on the right and left foot of the subject, but such a data for the F-scan system was not performed. Those results of the F-scan system were consistent with the previous studies mentioned in the literature review.

As comparing the control subject to the test subject only the F-mat and force plate systems were used and the differences between the two subjects include the following results: The control subject had a much smoother F-mat graph than the test subject. The test subject’s uninvolved limb (left) was also smoother than the involved limb (right) and the jagged graph may be indicative of a compensatory gait pattern due to decreased strength. In this study, the quantitative analysis of the data could not be performed due to the small sample size. A follow up study using a sample size of at least 25-30 subjects for the control and the test population is indicated.
IV. DISCUSSION

1. ADVANTAGE/DISADVANTAGE OF THE SYSTEMS

In this study, the validity and reliability of the F-scan and F-mat systems in measuring vertical ground reaction force was compared to the gold standard Force plate system. Each of these three systems have their own advantage and disadvantages as they are capable of obtaining different measurements. All of the systems are capable of measuring vertical ground reaction force, therefore this measurement was chosen to compare the validity and reliability of the three systems.

In addition to measuring vertical ground reaction force, the Force plate system is capable of measuring anterior-posterior shear and medial-lateral shear. Measurement of anterior-posterior and medial-lateral shear provides information such as changes in velocity, force at heel strike and toe off, and excursion of COG in medial and lateral direction.

The Force plate system is not capable of measuring foot pressure distribution. The F-scan and F-mat systems are unable to measure anterior-posterior and medial-lateral shear. The F-scan system measures foot pressure distribution at the foot-shoe interface. An advantage of measuring pressure at the foot-shoe interface is it indicates areas of high and low pressure on the foot, and allows for measurement of the effectiveness of orthotics, post-operative shoes, contact casts and other devices in redistribution of pressures on different areas of the foot. Measurements during bare-foot walking are not possible with this system as the sensor is designed to fit within a shoe.

The goal of this study was to compare the vertical ground reaction force data for the three systems. Since the F-scan measures the interaction of the foot with the shoe, and the F-mat and force plate measures the interaction of the shoe with the floor, we attempted to decrease the error caused by the interactions of the shoes by simulating bare foot walking. We placed the F-scan sensor on the bottom of the subject’s foot and secured it with a thin sock. The sock affected the foot-surface interface, however to a lesser extent than a shoe would have. An inherent difficulty with this method of data collection is the F-scan system is designed to lie flat in a shoe and does not conform to the curves on the bottom of a subjects foot. The control subject broke the sensor during each attempted trial, therefore data on the control subject for the F-scan system was not collected. The test subject also broke several sensors when her uninvolved foot was tested.

The F-mat system measures foot pressure distributions at the shoe-surface interface or the foot-surface interface if the subject is bare foot walking. Unlike the F-scan, this system unable to measure pressures at the foot-shoe interface. Advantages of this system compared to the F-scan system include:

1. The F-mat sensors are the same for all trials. There is no error caused by changing sensors between subjects and trials.
2. The F-mat sensors are more durable than the F-scan sensors. Sensor malfunction caused by temperature changes, sweating, or bending of sensors is less likely to occur in F-mat system.
3. The F-mat system can measure foot pressure during bare foot walking.
4. In this study, the F-mat system was a more reliable system than the F-scan system for measurement of vertical ground reaction force as compared to the Force plate.

2. RELIABILITY AND VALIDITY OF THE SYSTEMS

For the control subject, the F-mat system has
good validity and reliability when compared with the Force plate system, and was slightly less for the test subject. In observing the ground reaction force curves, the F-mat system consistently showed a delay in time to reach the first maximum point (loading response), and reached the second maximum point (terminal stance) before the Force plate system. The minimum point (midstance) correlated well for all three systems.

As mentioned above, data for the F-scan system was not collected for the control subject due to the breaking of the delicate F-scan sensors when used without a shoe. Different sensors were used to record data on the right and left foot of the subject due to the initial sensor breaking after transfer from the right to the left foot. The results indicate the sensors are fragile and give inconsistent results when different sensors are used. The sensor used on the subject’s right foot gave maximum of 43.5 lbs. This reading is not valid as the subject weighs 100lbs. The sensor should indicate at least 100 lbs during loading response and terminal stance. In previous studies, the sensitivity of the F-scan decreased with repeated trials. The F-scan sensors used in this study were previously used in other studies for an undetermined number of trials. This may account for the poor validity observed for the trials on the subject’s right foot.

3. CONTROL VS TEST SUBJECT

When comparing the control subject to the test subject only the F-mat and Force plate systems were compared and differences between the two subjects include the following:

1. The validity and reliability of the F-mat system was greater for the control subject than the test subject.

2. The control subject had higher ground reaction forces during loading response and terminal stance and lower ground reaction force during midstance as compared to the test subject. (The control subject had greater changes in the vertical ground reaction force than the test subject). There was no significant difference in the ground reaction force of the involved and uninvolved limb on the test subject as measured by the F-mat and Force plate systems.

3. The control subject spends less time in stance compared to the test subject. The control subject spent 0.59 and 0.57 seconds on the right and left foot respectively. The test subject spent 0.66 and 0.6 seconds on the involved (right) and uninvolved (left) foot respectively. The difference between the test subjects stance time on the involved versus uninvolved foot is significant.

4. The impulse experienced by the control subject was greater than the test subject. The control subject had higher maximal (loading response and terminal stance) and lower minimal (midstance) ground reaction forces, and decreased stance time when compared to the test subject. The increased force over a shorter time translates into greater impulse experienced by the control subject. As seen on the graphs, the slope of the graphs for the control subject is steeper.

4. STUDY LIMITATIONS

Limitations that may have affected the results of this study include:

1. In this study, the trials for each foot were averaged. Interpreting data in this way does not allow for measurements of inter trial reliability. Comparing the data and graphs for each trial would indicate variability between trials.

2. The inability to obtain data on the control subject for the F-scan system. Future studies may consider using a shoe with a thin sole such as a ballet slipper to decrease the potential for breaking the F-scan sensor.

3. Changing sensors for the right and left foot of the test subject caused inter sensor reliability
error. Optimally one sensor would be used for all trials on each subject. The use of previously used F-scan sensors also influenced the results of the study and may account for the poor validity noted on the test subject's right foot.

4. Out of the ten trials recorded for each subject, several of trial did not have complete data. During several trials, the researcher recording the data initiated data collected after the subject contacted the floor. Trials with incomplete data were not included in this study. Future studies may need to incorporate more trials into their study to allow for trials with incomplete data, or they may devise a better timing system to assure data are not lost. For this study, one researcher would count off the subjects’ steps. On the step prior to contact with the F-mat and Force plate systems, the researchers collecting data for the F-mat and F-scan systems began recording. Initiating recording two steps prior to contact with the F-mat and F-scan may eliminate this error.

V. CONCLUSION

In conclusion, if this study were performed while using a sample size of at least 25-30 subjects, this study would lead us to reject our first hypothesis that states the ground reaction force for the F-scan will show no statistically significant difference when compared with the Force plate.

The second research hypothesis which states the ground reaction force for the F-mat will show no statistically significant difference when compared with the Force plate would be accepted. The F-mat was more reliable when testing the control subject compared to the test subject. Third hypothesis that states there will be a significant difference in the ground reaction force for the control versus test subject would be also accepted. The control subject had an increased ground reaction force for each foot when compared to the test subject.

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