

## An Evaluation of the NewStep Algorithm for Diagnosing Proximal Orthopedic Conditions Utilizing Plantar Foot Force

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### Abstract

The authors review a new algorithm relating plantar foot forces with the development of proximal orthopedic maladies. The algorithm divides the foot into a number of discreet areas and the relationship between the forces applied to each area both ipsilaterally as well as contralaterally feed the evaluation. In addition, deviation of the center of gravity plays a role in evaluation of the algorithm. The authors present a blinded study with 200 subjects all presenting with proximal orthopedic complaints including knee pain, low back or hip pain, or upper back or neck pain. The evaluator scored 90% in positively predicting the subject's complaints, based on their foot scan. The results were independent of age, gender, or number of complaints presented by the subjects. The evaluator utilized strict adherence to the terms of the Newstep algorithm when making his diagnoses, and was encouraged not to overdiagnose. The algorithm is used by Newstep to develop a treatment protocol utilizing their active system. While this study did not evaluate the treatment aspect of the Newstep algorithm, the one to one relationship between the diagnostic aspect and therapeutic aspect, point to the fact that the treatment utilizing Newstep would also be efficacious.

**Keywords:** Orthopedic disease; Gait analysis; Inspiratory muscle training; Maximal inspiratory pressure; 6-Minute walk test

### Introduction

Orthopedic disease consists of any disorder or injury to bones, joints, tendons, ligaments and muscles. The diagnosis is often complicated [1-4]. The "Kinetic Chain", describes the pathway of movement and its connection, from the big toe through the jaw. This pathway can be traced during gait and predict disease at another site. Often, diagnosis is delayed, because of the need for expensive or complicated testing. Very little work has been done to correlate changes at the beginning of the Kinetic Chain, with outcomes in more proximal anatomic locations [5-7].

Gait analysis has been shown to be an objective measurement tool to assess pain, function and quality of life in a host of orthopedic conditions [8]. Patients with abnormal gait patterns have been found to suffer from impaired physical function and pain [9,10]. Studies have shown that by altering the center of pressure, and changing the vector trajectory during stance and gait lead to a reduction in symptomatology [11-13]. Asymmetry of the lower extremity exposes the body to excessive and unbalanced loads, having a negative impact on stance and gait and increasing the risk of the development of joint disease [14,15].

New Step has developed an algorithm with the goal of evaluating static plantar ground reaction force patterns to accurately predict or diagnose proximal orthopedic complaints. This study is a multi-center, open label trial with independent evaluation of the data collected. The aim of this study is to investigate whether proximal musculoskeletal complaints can be predicted accurately by measuring ground reaction forces of the foot.

### Methods

#### Study population

Two Hundred subjects were enrolled in the study. The subjects were culled from the student and faculty population at the New York College of Podiatric Medicine, as well as the patient population and faculty and staff at the Foot Clinics of New York. Attention was given

to try and equalize the subjects by gender and age range. Subjects were enrolled as long as they registered a complaint of pain in either knee, either hip or side of the lower back. Subjects were thus able to score anywhere from 1-4 complaints.

#### Study equipment

Subjects were asked to stand on a gait platform (Aetrex Inc. USA) for 10 seconds. This procedure was repeated twice and the second testing was recorded. The Aetrex gait platform was selected for its ease of use, portability and reproductivity of results. It is an FDA approved device and has been clinically verified and validated and used in many clinical trials.

#### Study design

IRB approval was attained (Salus IRB; Austin Tx). This was a prospective blinded study with one arm and a single evaluator.

Subjects were asked to fill out a brief questionnaire regarding location (R/L Knee; R/L Hip or Low Back), frequency (never, sometimes, always) of their pain, as well as severity (VAS score) of the pain. Subjects were then asked to stand on the force plate/gait platform for a scan of their feet. The results of the foot scans were recorded. Figure 1 shows an example of a recorded foot scan.

A single evaluator was recruited to review all of the foot scans. The evaluator was well versed in the Newstep algorithm, and was asked to apply it to the evaluation of the foot scans. The evaluator was given a blank questionnaire, identical to the one completed by the subjects, and

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**Received** December 05, 2019; **Accepted** January 06, 2020; **Published** January 13, 2020

**Citation:** Rosenblum J, Corcoran M, Doh K, Yonemoto G, Bains S, et al. (2020) An Evaluation of the NewStep Algorithm for Diagnosing Proximal Orthopedic Conditions Utilizing Plantar Foot Force. J Nov Physiother 10: 423.

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asked to fill it out based on the foot scan he was shown. The results of the evaluations were reviewed and subjected to statistical analysis.

### Results

Figures 2 and 3 show the demographic distribution of the enrolled subjects. There was a non-skewed distribution of subjects by gender and age. Figure 4 shows the distribution of number of complaints reported by the subjects. Figures 5 and 6 shows the results for the evaluator

scoring of the Newstep algorithm. The Newstep algorithm was able to positively predict/diagnose more than 92% of the complaints.

Statistical analysis showed that the results were statistically significant ( $p < 0.01$ ). Statistical analysis showed that age, gender, number of complaints, frequency of complaints or severity of complaints had no statistical effect on the results. There was no correlation of any confounding factors as well.

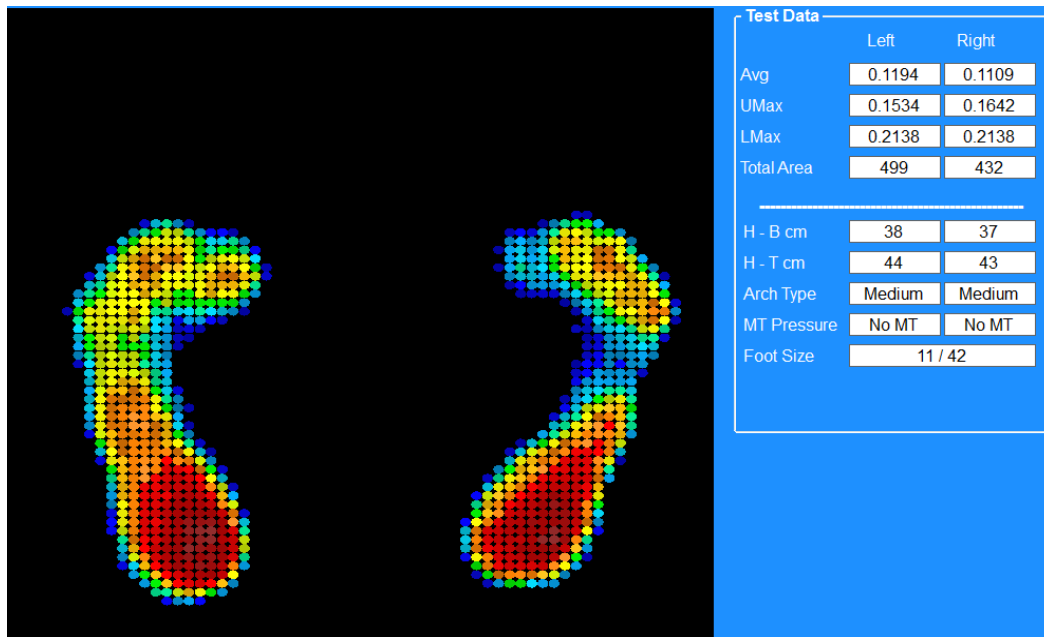


Figure 1: Demonstrative Gait Plate Plantar Force Analysis.

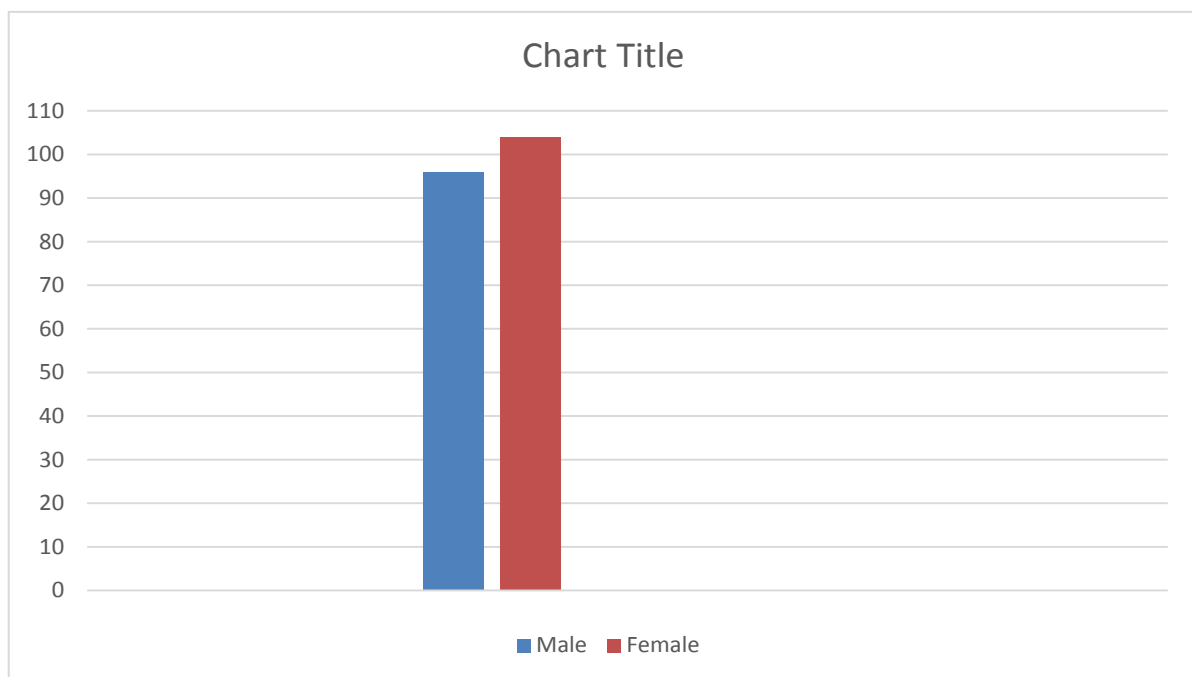


Figure 2: Subject Distribution by Gender.

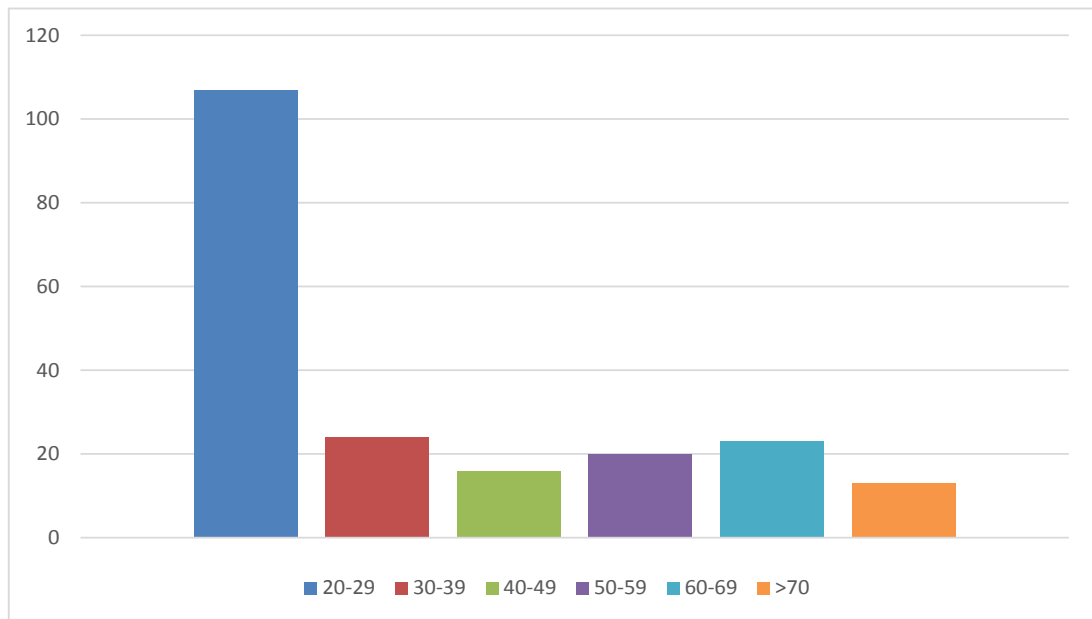


Figure 3: Subject Distribution by Age.

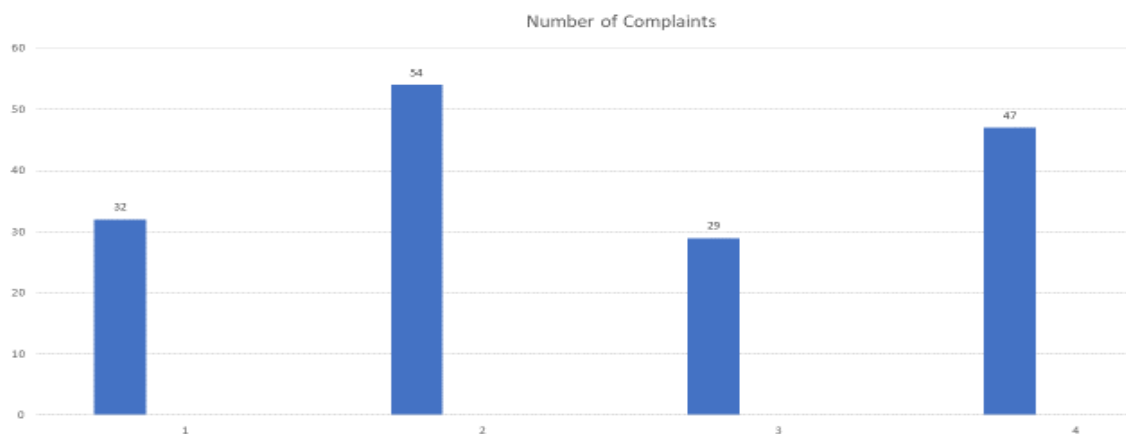


Figure 4: Distribution of Complaints Reported by Subjects.

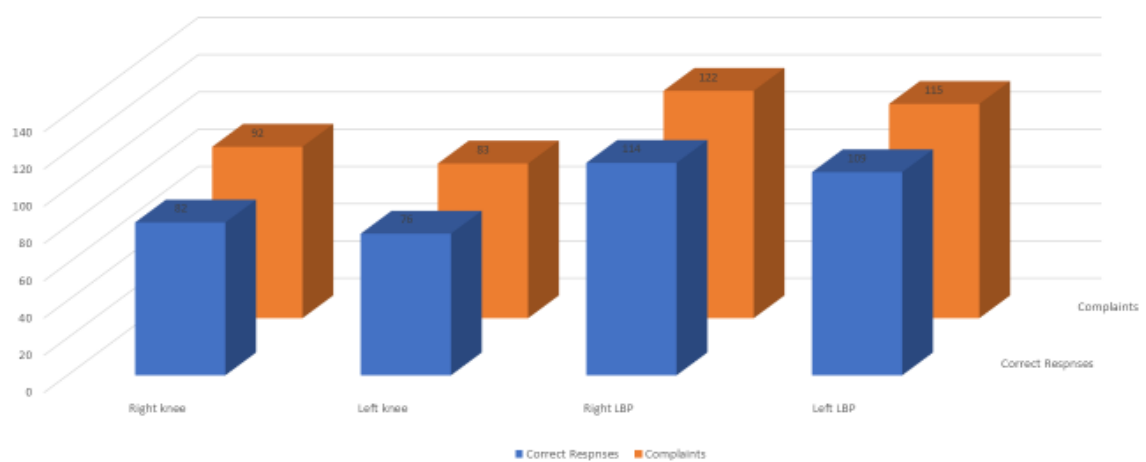


Figure 5: Distribution of Responses Versus Complaints By Location.

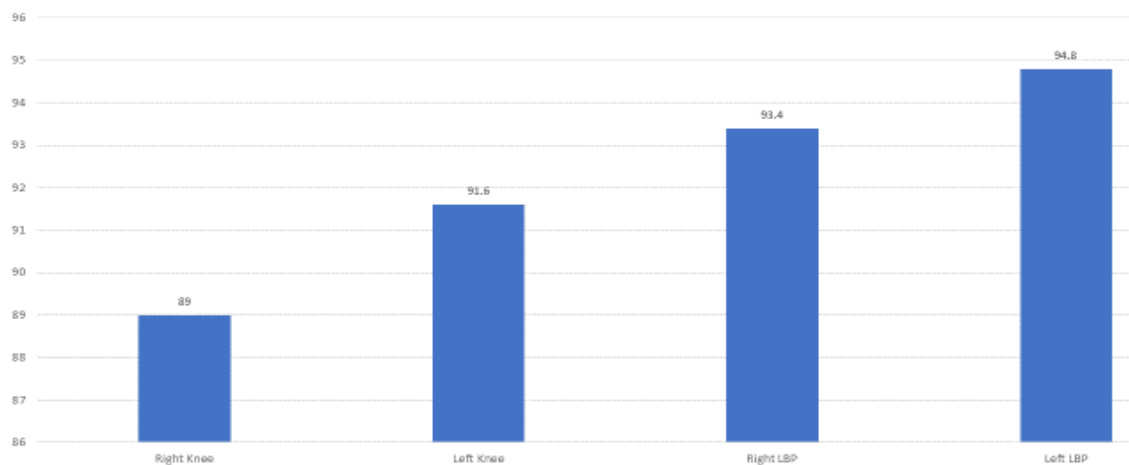


Figure 6: Percent Correct Reporting By Location.

## Discussion

This study evaluated the efficacy of the Newstep algorithm for correlating measured plantar forces and its predictive and diagnostic accuracy for more proximal orthopedic disease. While the connection between plantar force and proximal conditions is well established, a fundamental understanding of it, or a structured explanation of how and why is not readily available. The Newstep algorithm is posture based and is a two-part system. The first aspect of the algorithm is diagnostic. By dividing plantar force into a discreet (and limited) number of areas, and combining it with forward/ backward as well as right- left listing of balance, affecting the center of gravity in both the X and Y axis of stance, the algorithm can predict and explain the development of conditions in more proximal joints. The second part of the algorithm is therapeutic. By correcting these forces, postural, and balance anomalies, with the Newstep insole system, these proximal conditions can be improved and even healed. The therapeutic portion of the algorithm is built completely on the diagnostic part of the algorithm.

This was a well- developed blinded study which assiduously tested the diagnostic aspect of the Newstep algorithm. The sample size was large and diversified enough to be representative of the population suffering from orthopedic complaints. The questioning was specific enough to remove ambiguity from both the respondents and the evaluator. The only point of evaluation that could have been trifled with was had the evaluator relayed a positive response for all four complaints for every subject. This way the evaluator would have scored a 100% correct response rate. In review, the evaluator only relayed a five positive response less than 10% more often than when it was reported by subjects. This further attests to the validity of the protocol as well as the algorithm.

By the significantly accurate rate of response of the evaluator in the diagnostic side of the algorithm, it would be logical to predict that the therapeutic side of the algorithm would be equally successful. That is to say, while not all treatments effect a positive response, even when they are the correct treatment, utilizing the Newstep therapy system, based on the diagnostic algorithm would have a high rate of success. A clinical trial of the therapeutic system would be in order to further prove that, but as the therapy is based directly on the diagnostics, it stands to reason that it would also be successful.

## Conclusion

The Newstep Algorithm is a reproducible, easy to use tool to predict, and diagnose proximal orthopedic disease utilizing only plantar force patterns. The algorithm can be applied to existing technologies and

has a short learning curve. The algorithm is logical and can be further utilized to diagnose or predict development of other problems along the kinetic chain. Use of the algorithm would be beneficial as part of an overall evaluation when a complaint is presented to a physician.

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