Comparison of Langer Biomechanic's DynaFlange™ to Traditional "Legacy" Rearfoot Posted Orthotics

This study demonstrates the advantages of these devices.

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Background

Motion control, energy return, balance, stability, and comfort are some of the key words used in preparing for orthotic intervention. The traditional extrinsic rearfoot post is typically used to stabilize and sometimes restrict movement of the foot, so as to provide relief of clinical symptoms.[1] The so-called "legacy" post can also impede the natural reaction to the environment, and not encourage as much natural or barefoot, and un-braced, motion. Rearfoot posts consist of material added to the underside of the orthotic shell's heel with a goal of increasing the support and "platformed" area for stabilization and motion management at heel contact. However, no studies have compared their quantitative function or comfort to that of more dynamic orthotic devices, an example of which is Langer BioMechanics' DynaFlange™, invented by Dr. Jay Segel.

Dynamic orthotics are designed to control motion not only at heel contact but throughout the gait cycle. Dynamic orthotics work to facilitate motion, store and distribute energy or loading symmetries. Additionally, they are responsive and adaptive throughout the entire gait cycle, so as not to focus in one singular area, which might otherwise force associated areas to become compromised due to over-compensations. Adding the mechanics of flexible, dynamic bounce, while maintaining control where it otherwise might not be allowed, and mitigating the localized rigidities of posts can translate to an innovative idea. Does the aspect of control hold up, though? Will the responsiveness of a dynamic orthotic follow through where it is needed?

The following study was completed using Noraxon's Force Distribution Measurement Treadmill (FDM-T) to measure differences in continuous gait parameters for rearfoot posted orthotics, noted as "legacy" posts, and the dynamic orthotic, specifically, DynaFlange™.

The DynaFlange™ controls foot function during stance and ambulation by absorbing shock in the gaps that form between an orthotic, shoe or heel cup and the DynaFlange™ 3-dimensional plate. Its flanges dynamically deform at impact, causing the gaps between the concave heel cup and the convex DynaFlange™ to interact, providing foot and ankle protection, repositioning and motion control while dynamically absorbing shock. It then returns to its original state, which stabilizes and propels the foot actively. DynaFlange™ is active at stance phase and earlier in gait cycle allowing improved biomechanicals when compared to some other orthotics.[2]

Methods

23 subjects were tested within 48 hours. All were without acute, inhibiting symptoms or pathologies. Subjects were all previously scanned for correct device size, and legacy-posted orthotics (abbre-

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New Concepts and Studies

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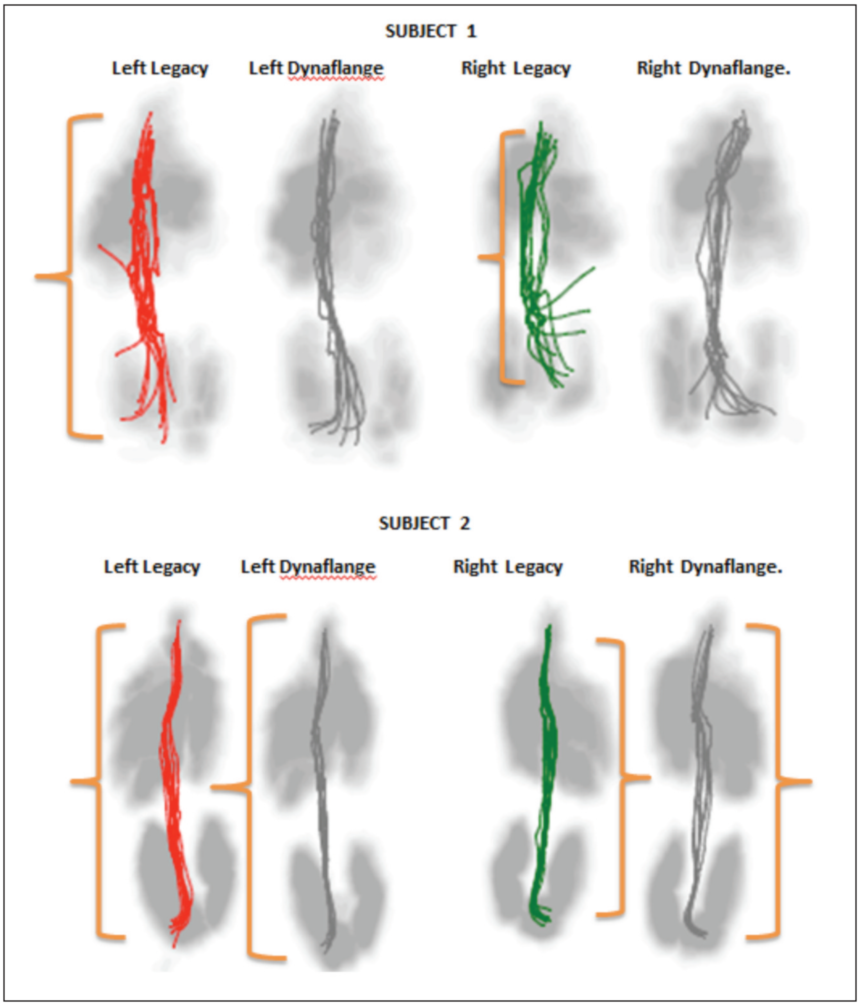

Figure 1: Two different subjects illustrating lengthened gait lines for both single support and stance—bilaterally, along with reduced deviations between strides, and improved left to right symmetry. This explains the ease of ambulation, especially in relation to the sagittal plane progression

viated L) and DynaFlange™ (abbreviated D) orthotics, made either of a composite or of a plastic (C or PE), were custom manufactured, specifically for testing.

Testing was completed on Noraxon's FDM-T system for stance and gait analysis. The force distribution measurement treadmill makes it possible to control the speed, walking surface, and environment while measuring all temporal and spacial gait parameters along with complete kinetics, pressure and ground reaction forces averaged and segmented. The FDM-T system has over 5,300 pressure sensors in a 150 x 50 cm area, built into the deck of the treadmill under the belt, thus subjects are not limited in their foot placement, deformities, orientations, or gait styles. The unit is a proprietary technology developed by Zebris to automatically stabilize the belt for accurate data acquisition from initial contact during walking or running gait through gait roll-off over any number of strides.

Upon arrival, instructions were provided and a questionnaire on any pre-existing variables or symptoms along with mention of ease of comfort on a treadmill, age, and weight, was completed, along with data release form. Prior to any measurement being taken, the auto calibration button was activated, and subjects were asked to walk for a few minutes to obtain comfort on the FDM-T. After a comfort level was achieved and natural gait was maintained, recording one was completed at 1.5 kph with patient facing forwards, arms relaxed, eyes ahead. Data for the recording in regular sneakers was saved. The second recording was then made for the same length of time at a subject-chosen speed. Data recorded for the second recording in regular shoes was saved with the speed denoted.

Following this first test, while resting off the treadmill subjects were asked to remove their standard, everyday insert, and replace with their custom legacy post or DynaFlange™. They were asked to again reach comfort treadmill level prior to recording and maintain consistent gait for 30 seconds at 1.5 kph, and then at their maintained chosen speed. The procedure was then completed again for the remaining device, including rest, then the initial walk on the treadmill as warm-up.

Once the 6 recordings of walking were made there was a summary test completed of lateral stepping—left and right—initiating from a stance with feet shoulder width apart.

Summary of Tests

I. Dynamic Gait: Regular shoe (R) without custom orthotic; 1.5 kph and speed of choice based on comfort

II. Dynamic Gait: Post legacy (L) Orthotic; 1.5 kph and speed of choice based on comfort (made either of C or PE)

III. Lateral Side-Step: Post legacy (L) Orthotic (made either of C or PE)

IV. Dynamic Gait: Post DynaFlange™ (D) Orthotic; 1.5 kph and speed of choice based on comfort (made either of C or PE)

V. Lateral Side-Step: Post DynaFlange™ (D) Orthotic (made either of C or PE)

Results and Discussion

Measurements with the DynaFlange™ showed longer roll-throughs, lengthened steps, dispersed impacts with increased loading responses, and more balanced, less duck-footed, and more controlled movement. All were objectified reactions which subjects did not have with the legacy post. Based on automatic software reports of direct comparisons on 30 seconds of strides, averaged for each of the 23 subjects, the following numerical results were found for the differences between DynaFlange™ and the legacy post.

Center of Pressure Analysis

With DynaFlange™, the average center of pressure gait line for the left and right side increased in length by over 4.3 mm when compared to the legacy posts. This translates to a significantly longer sagittal movement of ground contacts, and as shown by the loading rates, it was also a

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smoother overall transition, which is considered more efficient (see results of stance phase durations and loading rates). There were also more consistent patterns between strides as indicated by the reduced variations in the individual gait line lengths (Figure 1).

Aside from the gait line increasing for over 82% of the test subjects, average single support line on the left and right increased by over 2.74 mm, and also had reduced variability between strides, for the same percentage. A faster, more consistent, single support is indicative of the smoother propulsion into swing phase and single support for the opposite side. This is also supported by the increased length of the loading response, detailed below.

Results of the overall center of pressure traces, or cyclograms, highlight these improvements as well. DynaFlange™ increased stability and returned left and right symmetry, especially for this subject's right initial contact and loading response.

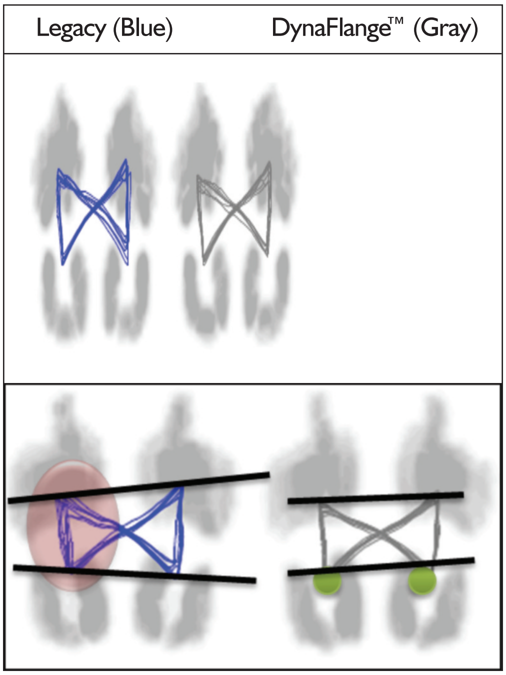

Figure 2: Example center of pressure cyclograms.

With DynaFlange™ (Gray), initial contact points are more consistently falling in the same localized area. With legacy (blue) the anterior/posterior landing location variations were greater. More consistent steps over horizontal ground, in a controlled environment, lead to more economical ambulation.[3]

Again, we see single support line lengths are more equal on the left and right sides with DynaFlange™ than without. Even though individual steps can be of varying length, it is crucial that the left and right sides of the body are responding equally to ground force reactions and maneuvering symmetrically if ambulation is horizontal along even terrain. The only time where it might make sense to have changes in step length and gait line lengths, as drastic as some examples without DynaFlange™, is around curves or uneven terrain.[4] DynaFlange™ "evened out" the patterns for subjects on the treadmill's controlled bed (Figure 2).

In looking at individuals' improvements in COP transitions it was also obvious there were some other useful mechanisms at work. For a few of the patients, one with bilateral arthritis at the ankles and a neurological disorder, and another pediatric subject, there was immense evening of the gait lines from left to right with DynaFlange™. There were significant increases in gait line lengths throughout, but the return to bilateral symmetry proved most obvious in these cases.

These results clarify that DynaFlange™ offers control in motion. Rather than accommodating or "making room" for subject pathologies, DynaFlange™ has mechanically responded, and streamlined entire gait control; beyond the typical, limited, stabilization at heel contact.[5] More subjective, verbal responses to the feelings encountered support this as subjects felt "springier", "lighter", "propelled", "like they had a bounce in their step", "they don't have cement blocks under their heels anymore", and just "more even."

Temporal and Spacial Parameter Analysis

In terms of the spatial and temporal aspects, subjects reported less strain in the midfoot with DynaFlange™ rather than with the legacy post. This is speculated to be due to the fact that the DynaFlange™ was deforming and providing energy to get the foot into re-supination and back off the ground, rather than ceasing the support after landing, and in some cases "blocking" the rest of the movement pathway.[6] There was a measured faster and smoother force and pressure transition to 100% gait cycle. During initial loading response (0-10%) to terminal stance phase (30-50%), shock absorption, efficiency and energy storage is of utmost importance, especially in preparation for off-loading or propulsion (Figure 3).[7]

Loading response begins with initial contact, the instant the foot contacts the ground. Normally, the

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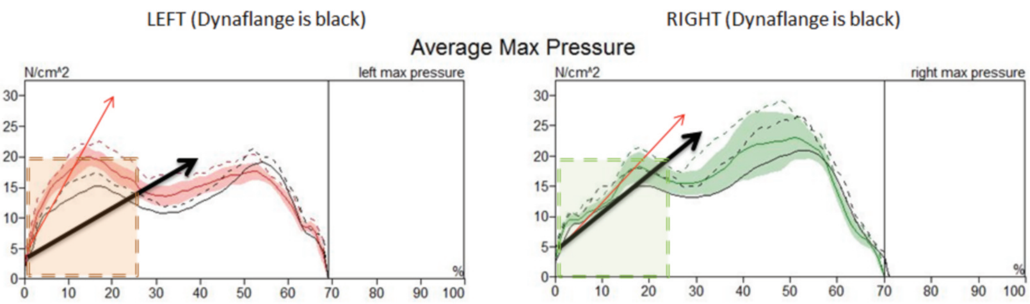

Figure 3: Left and Right Averaged Pressure Curves showing reduced rate of pressure increase (black slope) through to midstance for DynaFlange™ versus legacy (left-red, green-right).

heel contacts the ground first, except in patients who demonstrate pathological gait patterns. In pathological gait the entire foot or the toes may contact the ground initially.[8] Loading response ends with contralateral toe off, when the opposite extremity leaves the ground.

The loading responses can be seen quantitatively in the overall ground reaction curves and segmented curves. In Figure 4, the overall ground force reaction curves (GFR) for left and right objectively illustrate how the propulsion phase was sped up with the DynaFlange™

Kinematic Analysis

Rearfoot angle measurement is determined by monitoring the inversion and eversion of the calcaneous relative to the shank throughout ground contact. During midfoot to forefoot loading, the subtalar joint passes through neutral position, defined as a 0 degree rearfoot angle. At midstance, measurements should be as close to neural as possible. Past this point the subtalar joint progresses into pronation. DynaFlange™ encouraged a more neutral ankle position during the transition to forefoot loading (Figure 5).

Transverse Plane Movement Analysis

The lateral stepping test was the last test to truly determine the transverse plane motion control of the DynaFlange™. During lateral stepping with DynaFlange™ there was a measured average increase of almost 8 frames (8ms) in lateral shift from a supinated landing during the side step, when compared to the lateral step with the legacy post. This indicates it

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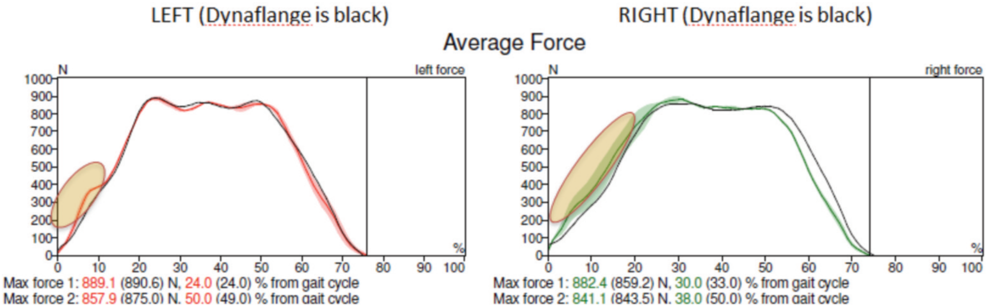

Figure 4: Left and right averaged GFR curves show reduced impact peaks at heel strike with DynaFlange™. There is also more steady loading which corresponds to increased control through mid-foot, leading to increased propulsion in DynaFlange™ (Gray), versus legacy (Red and green).

was a faster process to re-center after the supinated transversal motion (7.88 ms faster). This more immediate correction during the lateral sway leaves less time for compromised motions in the rearfoot, and greater forces higher up the kinematic chain.[9]

Subjects' center of pressure (COP) also covered a much smaller distance when DynaFlange™ was used. In fact, there was an average decrease of 47.39 mm. This decrease in path length was measured for over 80% of the subjects. It is evident that there were significant correcting characteristics for transversal plane motions with DynaFlange™. DynaFlange™ was managing the lateral motion and correcting more effectively, while guiding motion to take the shortest path from A to B.

The last stunning result from the lateral stepping test showed that the average velocity, mm/sec, of the COP movement increased by 17% over the legacy posts' average velocity during lateral stepping. Legacy posts did not provide the flexibility and dynamic response to center; rather, the numbers showed that movement was slowed and possibly compromised, especially at the ankle and even farther up the kinematic chain.

Conclusion

DynaFlange™ outperformed the legacy posts, with statistical significance far greater than the minimum standard, for increasing stride lengths and increasing loading response times. This becomes especially notable con-

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sidering earlier studies which have indicated that the function of an insert/orthotic is subject-specific. It was assumed that orthotics alter gait parameters in ways specific to every patient case. However, in this study there was a consistent and measured 82% change or higher, in one direction.

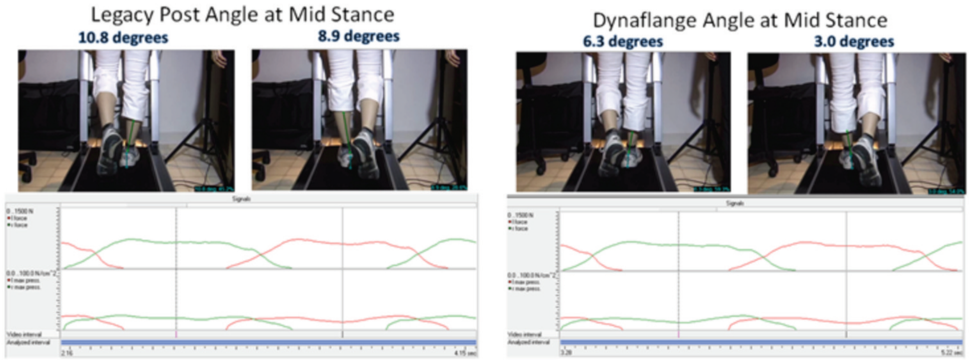

Figure 5: Sample of 2D kinematics from posterior view at midstance.

I. Stability and lateral movement in all planes are controlled so there is less variability of center of pressure when compared to movement in legacy posts.

II. Energy is stored and returned more efficiently so strides are longer, more neutral in position, and loading responses are faster, when compared to legacy posts.

III. Preparation for re-supination is faster, and preparation for propulsion to the next contact is faster, but at the same time more controlled.

IV. DynaFlange™ adds an aspect of consistency or control to all portions and planes of the gait cycle as detailed above.

We saw in our subjects, including those with more pliable arches and flexibility, that the DynaFlange™ allowed for energy to be stored and returned more efficiently leading to improved symmetry, and loading responses all while bringing spacial placements more towards neutral. Left and right deviations were nullified and the dynamic symmetry improved measurably. This was true across the board for all other varieties of foot types, not only flexible flatfeet, but all others tested. Results were also maintained across left to right sides, and timing for each segment was improved in a measureable pattern (increased or lengthened loading response, increased pre-swing, and decreased swing). This suggests that the DynaFlange™ is stabilizing and controlling motion through the entire gait cycle and also introducing use of the natural energies produced during early stance.

For further information on the data and reports compiled from the study, please contact Sally M. Crawford 480-392-4137, sally.crawford@noraxon.com. **PM**

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