Quality improvement study into the effectiveness of the semi-custom, prefabricated shoe insert program (Quadrastep System) at reducing complaints of discomfort in an industrial setting.

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A common source of reduced productivity and lost work time in the industrial setting is musculoskeletal discomfort in the feet, knees, hips, and low back. Even when working identical job posts, these symptoms can vary widely between employees, and could potentially be caused by intrinsic foot biomechanics coupled with long-term standing activities. Therefore, to prevent injury and reduce daily discomfort, one-size-fits-all approaches such as anti-fatigue mats or off-the-shelf shoe insoles may be less effective than treating each employee's specific biomechanical traits. The Quadrastep System is a prefabricated, semi-custom shoe insert system that bridges the gap between more expensive, fully customized orthotics and off-the-shelf options. We studied the effectiveness of the system in a large manufacturing plant by assessing and providing Quadrastep inserts to 28 volunteers. After 2 months of daily wear, 94% of these volunteers said they received some benefit from the inserts, while 52% reported full resolution of daily symptoms.

BACKGROUND AND OBJECTIVES

In the industrial work environment, daily discomfort in the back, legs and feet is commonplace. While much of this discomfort can improve with normal rest, without proper interventions, some symptoms can worsen, leading to lower employee morale, lost productivity, and potential injuries. For many years, ergonomists, physical and occupational therapists, engineers, managers, and employees have tried many different interventions (sometimes with success and sometimes with failure) to eliminate the forces that cause discomfort, yet the problem persists.

The importance of alleviating this discomfort cannot be overstated. One study performed by Stewart et al. (2003) showed that 12.7% of the total workforce experienced a loss in productive time during a given 2-week period due to a common pain condition such as headache, arthritis, back pain, and 'other musculoskeletal pain'. Workers who reported back pain and arthritis lost an average of 5.2 hours of productivity per week, while those who reported 'other musculoskeletal pain' lost an average of 5.5 hours of productivity per week. This study was not focused specifically on the industrial setting, in which the incidence of musculoskeletal disorders (MSD's) is potentially much higher.

It is also important to note the overall financial cost of workplace MSD's. In 1997, the CDC released a review of evidence for work-related MSDs which states, "The Institute in Medicine estimates the economic burden of WMSDs as measured by compensation costs, lost wages, and lost productivity, are between $45 and $54 billion annually". In 2004, The National Institute for Occupational Health and Safety (NIOSH) reported, "The manufacturing and services industry sectors together accounted for about half of all MSD cases".

For several years now, there has been a growing trend in health care away from one-size-fits-all solutions towards a more personalized approach to patient care. At the same time, preventative initiatives have become commonplace in all industries. Solutions such as ergonomic mats, off-the-shelf shoe inserts, general (non-employee specific) stretching and strengthening exercises have all become the norm, but due to their non-specific nature, while still being somewhat beneficial, they are likely to remain suboptimal solutions. The next step, then, if we are to keep pace with this trend, would be to consider each employee as an individual with their own specific musculoskeletal and biomechanical traits to address.

The Quadrastep System offers a step in the direction of preventative, personalized employee health care by offering a prefabricated, semi-custom shoe insert program that is both simple and cost effective, while still being capable of addressing individual employee biomechanical traits to reduce daily discomfort and protect against workplace MSD's. From the corrective shell designs to the different levels of posting, and even the varying density of materials used to make the inserts, we felt it was the most customized option within our price point to accomplish the goals we set out to achieve. In this quality improvement study, the employer chose to explore the effectiveness of the Quadrastep System in the industrial setting.

The system utilizes a 4-step assessment method and a clinical algorithm to categorize individuals into one of 6 unique foot types or 'Quads'. Each quad is letter and color coded for ease of selection and comes in 5 to 6 different size options. The Quad groups include: A Quad (yellow), B Quad (purple), C Quad (blue), D Quad (green), E Quad (light red), and F Quad (orange).

The "A-Quad" employee will present with an uncompensated rearfoot varus combined with a forefoot valgus, resulting in a combined foot condition referred to as "torque foot". The "A-Quad" orthotic provides specific management of this foot type with a deep heel cup, a lateral flare at the base of the 5th metatarsal, lateral forefoot posting with a 1st metatarsal cutout, and heel elevation for associated forefoot equinus.

Image 1.

The “B-Quad” foot presents with a mildly pronated rearfoot combined with a flexible forefoot valgus. It has a lower arch, and vertical or slightly inverted heel and adducted forefoot. The “B-Quad” orthotic provides management of this foot type with mild medial rearfoot posting and a mild medial skive, and a reverse Morton’s extension.

Image 2.

The “C-Quad” foot-type exists when an uncompensated rearfoot varus is coupled with a relatively neutral forefoot. A key distinguishing feature of this foot-type is an obvious toe-out gait pattern with a “normal” or slightly cavus arch height, and a “false” toe sign. The “C-Quad” orthotic utilizes moderate heel cup depth with a heel balancing post to “bring the ground up to the rearfoot” to manage the symptoms that may present with this foot type.

Image 3.

The “D-Quad” foot-type occurs when a compensated rearfoot varus couples with a neutral forefoot alignment. It presents with a vertical heel and a neutral toe sign. The “D-Quad” orthotic includes a deep heel cup, medial rearfoot posting and medial skive, and in some cases a metatarsal pad with soft top covers to offload the second metatarsal head.

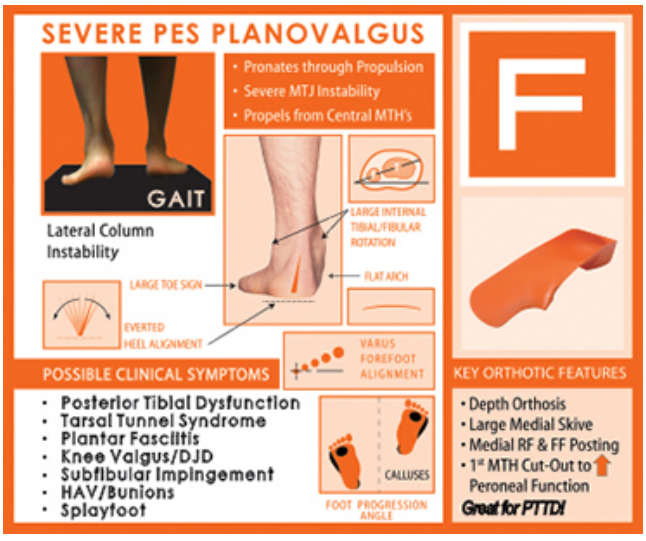
Image 4.

The “E-Quad” foot presents with a reverse-lasted shape created by an uncompensated rearfoot varus, combined with a structural forefoot varus. The arch is moderately pronated and there is a positive “creasing” toe-sign characterized by a sharp lateral foot angulation at the 5th metatarsal base. Orthotic recommendations for the “E-Quad” foot include moderate heel cup depth with medial rearfoot posting, and extrinsic medial forefoot posting with a 5th metatarsal head cutout.

Image 5.

The "F-Quad" can be referred to a Pes Planovalgus foot. The condition occurs when a severely compensated (pronated) rearfoot couples with an acquired forefoot supinatus, resulting in an extreme flat foot with a valgus heel and an abducted forefoot. Orthotic management for the "F-Quad" includes aggressive medial rearfoot posting and a medial skive with a first ray cut-out.

Image 6.



METHODS

Prior to the first assessment, required training in identifying the proper 'Quad' was undertaken by a licensed physical therapist. A 'fit kit' was then purchased which included a sample of each quad in each size available. Having this fit kit available during the assessment process was critically important because it allowed the patient to experience the fit and comfort of the insert prior to ordering. A 'widget kit' was also ordered to allow for any employee specific modifications that might need to be done to the insert. The kit includes self-adhering metatarsal mounds and materials to allow for small amounts of increased posting that may be required anywhere on the insert.

Also prior to the first assessment, a condition rating scale was developed to determine which employees were best suited for participation in the study.

Figure 1.

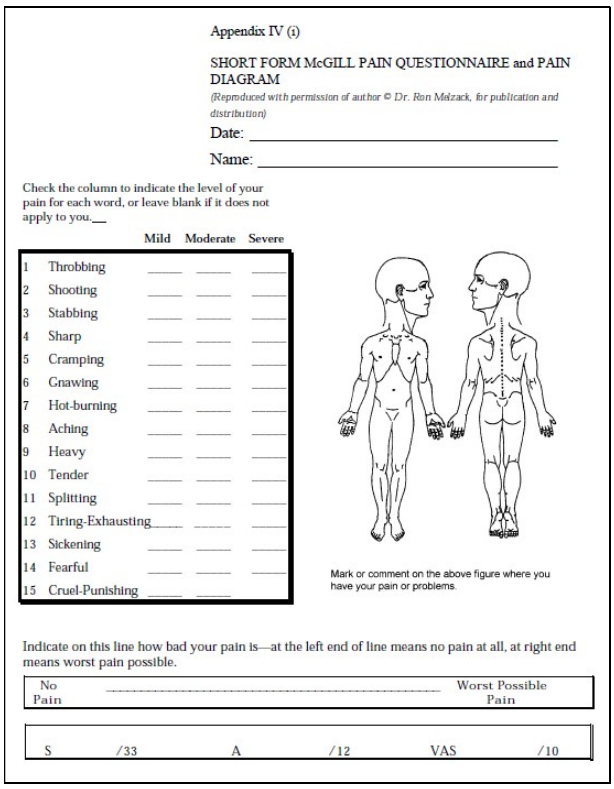
Condition rating scale.

1. No history of lower body musculoskeletal problems.
2. Mild supination or pronation with no history of musculoskeletal difficulty in back, legs or feet.
3. Mild to moderate pronation / supination with history of 1 episode of musculoskeletal dysfunction which required rest or conservative treatment but resolved over time.
4. Mild to moderate or severe pronation / supination with 2 or more (possibly recurring) episodes of musculoskeletal dysfunction which required rest or conservative treatment but has resolved over time.
5. Mild to moderate *occasional* (1 or more times per week) discomfort in the back, legs or feet which presents after long periods of standing and dissipates with rest.
6. Mild to moderate *daily* discomfort in the back, legs or feet worsens with long periods of standing and eases with rest.
7. Moderate to severe *daily* discomfort in the back, legs or feet which worsens with long periods of standing and does *not* ease with rest.
8. Complaints of daily musculoskeletal discomfort in back, legs or feet, that is severe enough that it is causing lost time at work and / or limiting hobby participation.
9. Reporting symptoms that are severe enough as to be considering / require surgery.
10. Post-surgical, crush injuries, congenital issues, etc.

To show that improvement could be achieved, ideal candidates were rated between 5 and 8 on the rating scale, although 2 employees who qualified as condition 9 were also included. Employees that rated 4 or below on the scale were considered poor candidates because they would not be experiencing regular symptoms, and therefore they would not be able to subjectively relate whether the inserts were beneficial. The only other criteria used to determine suitability was that the employee was injury free at the time of the assessment.

In total, 31 employees (16 men and 15 women) volunteered to participate in this study. Each assessment lasted between 15 and 45 minutes and was scheduled and performed during a normal work shift. The initial assessment began with the employee filling out a brief intake form including basic health and contact information, as well as a short-form McGill Pain Questionnaire.

Figure 2.



Appendix IV (i)

SHORT FORM McGILL PAIN QUESTIONNAIRE and PAIN DIAGRAM

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Date: _____

Name: _____

Check the column to indicate the level of your pain for each word, or leave blank if it does not apply to you.__

		Mild	Moderate	Severe
1	Throbbing	____	____	____
2	Shooting	____	____	____
3	Stabbing	____	____	____
4	Sharp	____	____	____
5	Cramping	____	____	____
6	Gnawing	____	____	____
7	Hot-burning	____	____	____
8	Aching	____	____	____
9	Heavy	____	____	____
10	Tender	____	____	____
11	Splitting	____	____	____
12	Tiring-Exhausting	____	____	____
13	Sickening	____	____	____
14	Fearful	____	____	____
15	Cruel-Punishing	____	____	

Mark or comment on the above figure where you have your pain or problems.

Indicate on this line how bad your pain is—at the left end of line means no pain at all, at right end means worst pain possible.

No Pain _____ Worst Possible Pain

S /33 A /12 VAS /10

Subsequently, a brief discussion of their condition(s) took place to understand their history and current symptoms, to determine their position on the rating scale, and to rule out any red flags (open wounds, acute injuries, etc.).

After the discussion, if the employee was an ideal candidate, then the 4-step assessment protocol for the Quadrastep System was initiated. The first and second step in the process involved the employee standing barefoot in resting calcaneal stance, while the assessor observed arch height and toe sign from both the anterior and posterior view. Photographs were taken from each perspective. Next, the employee was asked to walk barefoot on a treadmill while gait observations were made from a posterior perspective and video was recorded for roughly 10 seconds (3rd step). Finally, the patient was moved into a prone position on a plinth for the 4th step, which was to observe the callous patterns on the plantar surface of their feet.

Once the assessment was complete, the correct quad was determined. Although there were multiple times where an employee was a perfect match for one specific quad and no further sampling was required; far more commonly, the decision came down to 2 different inserts which were sampled by the employee both in standing and walking. Determining which insert would be most beneficial at that point typically came down to the apparent fit of the insert combined with the patient's subjective comfort level while standing and walking.

The information collected during the assessment process was then independently reviewed by a representative of the Quadrastep company. The examiners then compared their selections on the 28 respective cases and discussed the reasons behind each selection via phone conversation and/or email discussion. The relative ease of the selection process is underscored by the fact that there was agreement on 27 out of the 28 assessments performed. Upon completion, the correct inserts were ordered in bulk and were received at the facility within one week.

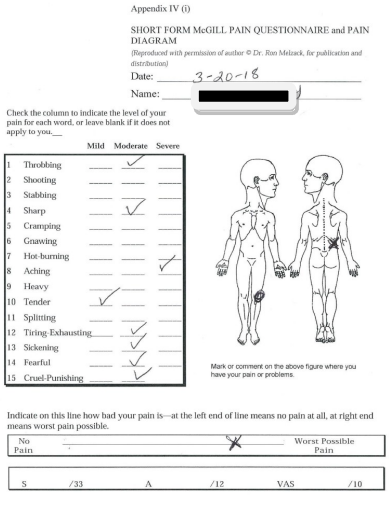
A 'fitting' visit was scheduled once the inserts were delivered. During this visit, the employee wore the inserts in standing and walking to ensure correct fit and comfort. The break-in process was then explained in detail, wear time expectations were discussed, and contact information was provided to the employee in case there were any future problems. A brief fitting assessment form was also filled out.

Periodic (typically every 2 to 3 weeks) visits were made to each employee during the trial period to discuss any problems that may have arisen with the inserts. Roughly six employees had difficulties which were typically resolved in 1 visit and had to do with improper quad selections from left to right (some people were a D on one side and a C on the other, etc.), improper size, or issues with break-in compliance. After 1 ½ to 2 months of extended wear, a third and final visit was performed, during which an exit questionnaire and a repeat of the short-form McGill Pain questionnaire was filled out.

For our purposes with the short-form McGill Pain questionnaire, we decided to assign a specific set of points for each column. A mark in the mild column was worth 1 point while marks in the moderate and severe column were worth 3 points and 5 points respectively. In example 1 (below), the initial assessment grid score rating would therefore be a 24. In example 2 (below) the initial grid score rating would be 27. This allowed for a more accurate representation of how impaired the employee was, and a more accurate measuring stick for level of improvement obtained by wearing the inserts.

Example 1.

Initial assessment



Appendix IV (i)

SHORT FORM McGILL PAIN QUESTIONNAIRE and PAIN DIAGRAM

(Reproduced with permission of author © Dr. Ron Melzack, for publication and distribution)

Date: 3-20-18

Name: [redacted]

Check the column to indicate the level of your pain for each word, or leave blank if it does not apply to you.__

		Mild	Moderate	Severe
1	Throbbing		✓	
2	Shooting			
3	Stabbing			
4	Sharp		✓	
5	Cramping			
6	Gnawing			
7	Hot-burning			✓
8	Aching			✓
9	Heavy	✓		
10	Tender	✓		
11	Splitting			
12	Tiring-Exhausting		✓	
13	Sickening		✓	
14	Fearful		✓	
15	Cruel-Punishing			✓

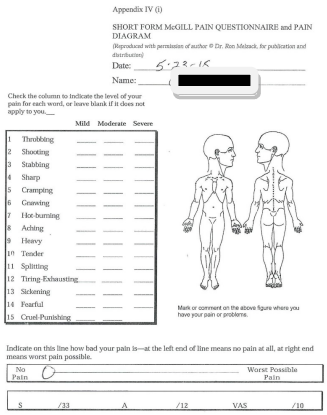
Mark or comment on the above figure where you have your pain or problems.

Indicate on this line how bad your pain is—at the left end of line means no pain at all, at right end means worst pain possible.

No Pain Worst Possible Pain

S /33 A /12 VAS /10

Final assessment


Appendix IV (i)

SHORT FORM McGILL PAIN QUESTIONNAIRE and PAIN DIAGRAM

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Date: 5-22-18

Name: [redacted]

Check the column to indicate the level of your pain for each word, or leave blank if it does not apply to you.

	Mild	Moderate	Severe
1 Throbbing			
2 Shooting			
3 Stabbing			
4 Sharp			
5 Cramping			
6 Gnawing			
7 Hot-burning			
8 Aching			
9 Heavy			
10 Tender			
11 Splitting			
12 Tiring-Exhausting			
13 Sickening			
14 Fearful			
15 Cruel-Punishing			

Mark or comment on the above figure where you have your pain or problems.

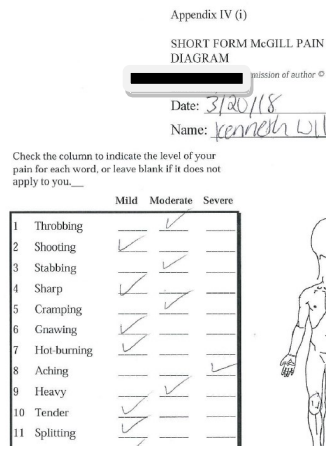
Indicate on this line how bad your pain is—at the left end of line means no pain at all, at right end means worst pain possible.

No Pain — Worst Possible Pain

S /33 A /12 VAS /10

Example 2.

Initial assessment


Appendix IV (i)

SHORT FORM McGILL PAIN DIAGRAM

[redacted] mission of author ©

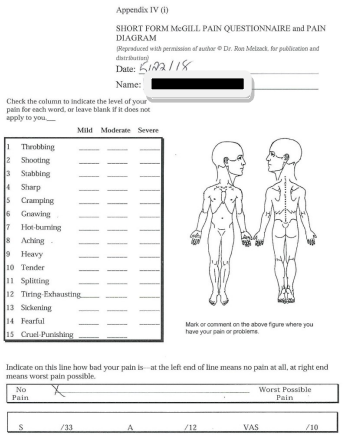
Date: 3/20/18

Name: Kenneth Ull

Check the column to indicate the level of your pain for each word, or leave blank if it does not apply to you.

	Mild	Moderate	Severe
1 Throbbing		✓	
2 Shooting	✓		
3 Stabbing		✓	
4 Sharp	✓		
5 Cramping		✓	
6 Gnawing	✓		
7 Hot-burning	✓		
8 Aching			✓
9 Heavy		✓	
10 Tender	✓		
11 Splitting	✓		

Final assessment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SHORT FORM McGILL PAIN QUESTIONNAIRE and PAIN DIAGRAM

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Date: 5/22/18

Name: [redacted]

Check the column to indicate the level of your pain for each word, or leave blank if it does not apply to you.

	Mild	Moderate	Severe
1 Throbbing			
2 Shooting			
3 Stabbing			
4 Sharp			
5 Cramping			
6 Gnawing			
7 Hot-burning			
8 Aching			
9 Heavy			
10 Tender			
11 Splitting			
12 Tiring-Exhausting			
13 Sickening			
14 Fearful			
15 Cruel-Punishing			

Mark or comment on the above figure where you have your pain or problems.

Indicate on this line how bad your pain is—at the left end of line means no pain at all, at right end means worst pain possible.

No Pain — Worst Possible Pain

S /33 A /12 VAS /10

The visual analog scale (VAS) scale was simply a 100-millimeter line and the markings by the employees were measured from the 0 to obtain the level of discomfort.

In total, 31 evaluations were performed, and of those 31, 28 employees were deemed to be ideal candidates for the program. Out of the three volunteers that did not receive inserts, one was given a rating of 10 on the condition rating scale due to congenital foot issues and was therefore not selected to participate. The other two volunteers required only a heel lift to manage a small leg length discrepancy. This intervention was enough to reduce their symptoms significantly without requiring a Quadrastep insert. Of the 28 who received the inserts, 24 followed the program through to the end, including filling out the initial and exit questionnaire and the initial and final short-form McGill Pain questionnaire. Four volunteers that received inserts did not follow through to the end of the program. Two of these volunteers did not feel the inserts were beneficial and when asked to attend a follow up visit, they declined and also failed to fill out the final paperwork. One volunteer received the inserts prior to starting a lengthy vacation and chose not to wear them after returning. One volunteer (the first one) did not fill out the initial assessment paperwork, and although he achieved significant relief from symptoms, it was not reasonable to include his results in the final tally due to not having the initial paperwork completed for comparison. The following results are based off those 24 people who completed the program.

RESULTS

The average total point value of the grid section of the questionnaire (referred to as the grid rating) pre-trial was 15.7. The average grid rating of the questionnaire post-trial was 2.7 for a total average improvement of 84%.

The average measurement of the VAS pre-trial was 44.8 millimeters (roughly 4.5 out of 10). The average measurement of the VAS post-trial was 8.9 millimeters (less than 1 out of 10) for an average improvement of 81%.

The following questions were posted on the exit questionnaire and the employees were asked to rate their answers in a 0 to 5 scale with 0 being the absolute worst and 5 being the absolute best.

1. How satisfied are you with the inserts? Average answer = 4.7 out of 5
2. Would you recommend the inserts to others? Average answer = 4.4 out of 5
3. Will you continue to wear the inserts daily? Average answer = 4.6 out of 5

The percentage of people who participated in the study that reported some benefit from the inserts = 94%.

The percentage of people who participated in the study that reported full resolution of symptoms = 52%.

The number of people in the study that were considering an MRI / surgery for their personal medical condition (a condition 9 on the rating scale) but were able to avoid it = 2.

CONCLUSION

In this preliminary quality improvement study looking at the effectiveness of the Quadrastep System at reducing complaints of discomfort in an industrial setting, a majority of employees (94%) received benefit from the inserts, and over half (52%) achieved full resolution of reported discomfort. Therefore, the system appears to be effective in reducing the subjective complaints of discomfort in employees within the industrial setting.

DISCUSSION AND COMMENTS

It is important to note that this quality improvement study did not utilize any specific objective measurements, and that it lacks the rigor of a double-blind, randomized controlled study. Future studies would be improved with the introduction of a control group which may consist of a simple cushioned insole that provides no correction. Also, expanding the number of test subjects to more significant percentage of the workplace population would be ideal, and controlling for shoe type would be critically important to any future study on the subject. Given this, the subjective results of the study in its current form seem to justify continued research in this area.

Of the employees who completed the study, there were 2 employees (mentioned previously) who, after being offered an intervention visit, declined, and decided not to continue wearing the inserts. In both cases, the employee was a type II diabetic. With this small of a sample size, it is not reasonable to conclude that diabetic employees are a poor fit for this type of insert. Perhaps they simply require a top cover modification or a narrower insert; however, more study is needed in this area.

It is interesting to note that a large subset of the employees in the study (16 out of 24) spent 90% or more of their workday standing / walking on anti-fatigue mats. The average initial VAS rating for these employees was 4.3. A smaller subset of the employees (6 out of 24) spent less than 10% of their time on anti-fatigue mats. Their initial VAS rating was 5.1. This leads to the notion that the anti-fatigue mat group experiences less daily discomfort than the non-anti-fatigue mat group by roughly 16%. There are a variety of factors that are not considered here that may also be contributing to these percentages, including the amount of time spent walking vs. static standing, differences in lengths of time spent on the mats, and the low number of employees in the non-anti-fatigue mat subgroup, but one could potentially assume that ergonomic mats are able to provide a marginal level of relief from discomfort on average. With the addition of the Quadrastep System, however, in both cases, the employees were able to see far more significant improvement in VAS scores; lowering the VAS ratings to 0.7 for the larger subset of employees who stood on anti-fatigue mats most of the time, and 1.1 for the smaller subset who did not. This equates to an 84% improvement for the anti-fatigue mat group and a 79% improvement for the non-anti-fatigue mat group. In light of this, it is interesting to consider the cost-benefit ratio for purchasing and continual replacement of large numbers of anti-fatigue mats vs. the Quadrastep System if the goal is to reduce overall discomfort and protect against injury.

Also, with regard to anti-fatigue mats, it is interesting to note that while research has shown conclusively that the type of surface the employee walks on has a direct impact on their comfort level (Cham and Redfern, 2001), there is little to no consensus over what type of surface is optimal for everyone. An article by Wiggerman and Keyserling from *Human Factors - The Journal of the Human Factors and Ergonomics Society* - August 2013 states that 'The general conclusion that can be drawn from previous studies is therefore somewhat limited: that very hard surfaces are undesirable for standing and that very soft surfaces may also be undesirable. There is currently no method for predicting the effectiveness of a particular mat in mitigating discomfort.' For much the same reason that there is no universally 'best' corrective lens for the multitude of vision problems we face, the simple reason that there is no universally 'best' surface to stand on may be that people's feet are different and they require different levels of support and cushioning. More research is needed in this area.

APPENDIX

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