Effect of a Discomfort-Inducing Textured Insole on Balance and Gait

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Bachelor’s Degree, Peking University, China, 2007

THESIS

Submitted as partial fulfillment of the requirements for the degree of Master of Sciences in Rehabilitation Sciences in the Graduate College of the University of Illinois at Chicago, 2015

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Chapter 1. Introduction

Stroke is the leading cause of long-term disability in adults and one of the leading causes of death in the world. ¹ There are approximately 800,000 people who experience new or recurrent strokes annually. Stroke related costs were over 30 billion dollars in 2014 and there is a prediction for the cost to increase over the next 10 years. ² There are many complications for individuals who have had a stroke, including paralysis or loss of muscle movements, difficulty talking or swallowing, memory loss or difficulty of thinking, emotional problems, changes in behavior and self-care ability, and pain or numbness. Additional major complications of people with stroke are paralysis or muscle weakness on the affected side, asymmetrical weight distribution, and impaired postural control. Thus, individuals with stroke tend to use their healthy side more than the affected side in their daily activities. ³

One of the rehabilitation goals for those who have had a stroke is to assist them in regaining and retaining their ability to deal with daily tasks. Traditionally physical therapy provided to individuals with stroke focuses mainly on restoration of the mobility and stability of the trunk and lower limbs. Moreover, the majority of current physical therapy approaches are based on providing positive reinforcement. ⁴,⁵ Positive reinforcement happens when caregivers or therapists provide motivating items when the caretakers or patients exhibited the desired behaviors. The methods of positive reinforcement have been shown to be a very efficient tool in rehabilitation of the elderly⁶,
individuals post-stroke\textsuperscript{7}, individuals with Parkinson’s disease\textsuperscript{8}, and other groups \textsuperscript{9}.

Besides approaches focused on positive reinforcement, negative reinforcement approaches have proven to be effective in rehabilitation of individuals with different neurological impairments. For instance, Constraint-Induced Movement Therapy (CI therapy) is broadly performed in the clinics today. CI therapy is used to constrain patients to use their less-affected side of the body while performing certain tasks so that the patients would tend to make more movements on the more-affected side. CI therapy has been applied successfully within the brain injury population\textsuperscript{10}, people with multiple sclerosis\textsuperscript{11}, and individuals with chronic CVA\textsuperscript{11}. The negative reinforcement could be applied to remind people walking with narrow base of support (BOS) to widen their BOS. \textsuperscript{12} Based on previous studies\textsuperscript{13}, the textured insoles were used to provide negative feedback to healthy individuals. The outcome of the study showed that using the negative feedback induced by discomfort under the sole of one foot results in subjects shifting their body weight toward the no-insole side while tested in static or dynamic conditions. Thus, the outcome of this research confirmed that the concept of using discomfort induced by a textured insole could potentially be used in the rehabilitation of individuals with asymmetrical stance and gait, such as individuals with stroke.

The previous study using textured insoles provided preliminary data on the immediate improvement of gait symmetry in four individuals with stroke\textsuperscript{13}. However, due to a small number of subjects enrolled, the outcome of that study could not be generalized to the population of individuals with stroke. Thus, there
are several questions that draw our attention: “Would the results of a larger study be similar to the outcome of a previous study showing that individuals with stroke using a textured insole on their less-affected side tend to lean on their no-insole side (affected side)”, “Would individuals with stroke be able to use different types of textured insoles (for example with different dimensions of the protrusions)?”, and “Would textured insoles of different design provide similar results in terms of improvement of gait and stance symmetry when the individuals with stroke use them?” Thus, our first hypotheses is that the results of the study involving a larger sample of subjects would support the outcome of a previous study and the application of the textured insole would improve stroke victims’ postural control and gait symmetry. The second hypothesis is that individuals with stroke will be able to use textured insoles of different designs. The third hypothesis is that regardless of the design, textured insoles could improve symmetry of postural control and gait in individuals with stroke. As an additional exploratory question, we will also look at the differences in the outcomes due to the use of different types of insoles.

**Literature Review**

**Static Balance and Stroke**

Stroke is the leading cause of disability in adults. Stroke affects posture control in standing and in movements. The study conducted by Yanahara et al. 14 revealed that the recovery process of standing posture control, especially the weight bearing asymmetry, was diminished in the first 2 weeks of when a stroke occurred, but the asymmetry did not improve afterwards. Geurts et al.15 also reported that the weight bearing asymmetry diminished in the first 4 weeks
after the stroke, but did not improve thereafter. The studies these authors conducted were focused on the acute individuals with stroke, yet the results clearly reveal that the improvements were limited after the acute stroke stage. The results of both Yanahara and Geurts studies showed that the reported weight bearing asymmetry in individuals with stroke is because they tend to rely on their less-affected side more than their more-affected side.

There were several studies focusing on how to improve static balance in individuals with stroke using therapeutic training programs. Thus, Bayouk et al.\textsuperscript{16} studied the individuals with chronic stroke participating in the 8-week task-oriented exercise program and reported that the study participants improved their stance and dynamic balance after training. Similar results were obtained in another study involving high intensity strength training for 12 weeks: individuals with stroke improved their stance balance post training (Weiss et al.\textsuperscript{17}). Aside from the training programs that are proven to be effective for rehabilitation, there are several researchers focusing on assistive devices that could improve the static balance in individuals with stroke. Thus, the outcome of the study investigating the role of a shoe lift under the affected limb of individuals with hemiparesis due to stroke showed immediate improvements in static and dynamic balance.\textsuperscript{5,18}

However, the mechanism of the shoe lift \textsuperscript{5,18}and lateral-wedged insole\textsuperscript{19} are different from the T-insole in this study. Studies using a lift were based on the idea that when lifting the insole on the less-affected side, the body weight was redistributed mechanically toward the more-affected side which in turn, led to improvement in the symmetry of static balance. Quite the opposite, the T-insole under the sole of the non-affected lower extremity does not provide a lift,
instead it creates discomfort thus requiring the user to actively avoid that discomfort by shifting the body weight to the more-affected side.

**Gait and Stroke**

Hemiparetic gait pattern is characterized by decreasing gait velocity, step length, and joint angular excursions. 20,21 Asymmetry in temporal, spatial, and kinetic gait variables was seen in individuals with hemiparesis due to stroke as well.22,23 Therefore, the improvement of gait asymmetry becomes one of the goals for rehabilitation in stroke victims.24

Several studies focused on how to train individuals with stroke to regain their walking ability and/or improve their gait pattern. In the research by Visintin et al. 25, the stroke victims included in the body weight support (BWS) training group showed improvement in walking speed and walking endurance. The study conducted by Jonsdottir et al.26 was focused on how task-oriented electromyographic biofeedback (EMG-BFB) could be applied to improve gait pattern. EMG-BFB in a task-oriented approach is based on motor learning that would increase the peak ankle power and gait velocity. The results of the study revealed that using the EMG-BFB improved the peak ankle power and increased gait velocity. In the study by Teixeira et al.27, the researchers evaluated the effect of combining a training program with muscle strengthening and a regular physical therapy program for 10 weeks in improvement of gait pattern. The results showed that there were significant improvements of kinematic and kinetic measures, which also related to the improvement of asymmetry of gait patterns.
Traditional over ground training programs were not the only methods used to improve gait in the rehabilitation process for stroke patients. In the research of Mayr et al.\textsuperscript{28}, the use of Lokomat, a kind of a robotic assistive device, was proven to be effective in the rehabilitation of individuals with stroke. Thus, improvement after the Lokomat-based rehabilitation was seen in the outcome of many scales, such as EU-walking Scale, Rivermead Motor Assessment Scale, and 6-minute timed walking distance. The robotic assistive devices were considered promising for gait training in various research methods\textsuperscript{28-30}, yet the device itself is location-limited as a patient has to go to the clinical facility to use Lokomat therapy. Moreover, people needed to be supervised to use this device, and the use of Lokomat might be costly. Meanwhile, the T-insole use is not restricted by a certain location as it can be used even at home, and might lower the cost of therapy.

**Insole, Balance, and Gait**

Assistive insoles were applied to improve the balance in many different groups of patients. For instance, Christovão et al.\textsuperscript{31} applied a postural insole on children with cerebral palsy for balance improvements. The study participants using the insole showed improvement of the body sway and Timed Up-and-Go tests. The reported improvement could be interpreted that the postural insole allowed for better postural control, which in turn improved the gait pattern and static balance.

Other types of insoles could also be beneficial for improving postural control. Thus, the outcome of studying the effect of vibrating insoles demonstrated that such insoles could enhance the somatosensory sensation
under the plantar surface of the feet and improve the postural control in elderly people \(^{32}\) as well as in individuals with diabetic neuropathy \(^{33}\). Moreover, it was also reported that wedge and lift-like insoles could benefit the postural control in individuals with hemiparesis due to stroke \(^{5,19,34}\).

Other than the T-insole used in the current study, a contribution of several different textured insoles to control balance were studied in different research. In the study by Kelleher et al. \(^{35}\), the textured insole enhanced the sensation to the sole of the foot in individuals with multiple sclerosis (MS). The textured insole used in the Kelleher study provided sandpaper textured roughness and sensory feedback was expected. It is important to mention that in that study, two textured insoles were used. The results suggested that there were kinetic and kinematic changes while applying textured insoles. Thus, the textured insole in Kelleher et al. research improved gait pattern in the MS group.

In the research by Qiu et al. \(^{36}\), the textured insoles were provided to individuals with Parkinson’s disease (PD). The results suggested that the PD group benefited most by using the textured insoles and the improvement was seen while standing on a foamy surface with their eyes closed, which means the textured insole may improve postural stability for people with PD. The study directed by Kalron et al. \(^{37}\) focused on studying whether the textured insoles affected postural control and spatiotemporal parameters of gait and plantar sensation in people with MS. However, the results did not support the author’s hypothesis that the textured insoles did not alter static postural control, and induced limited changes in gait parameters.

The textured insoles used in the mentioned above studies were intended to create a different sensation in the soles of both feet. Thus, the insoles induced
feedback and the feedback improved balance control. It is important to note that none of the textured insoles used in the research mentioned above were intended to induce the discomfort on one side, which is the main conceptual approach in this study. Previously, research directed by Aruin et al.\textsuperscript{13} showed that the discomfort-inducing textured insole could alter the postural control and gait parameters in healthy individuals. Thus, this study is intended to further investigate if the discomfort-inducing textured insole would induce the symmetry of stance and gait patterns in healthy individuals. We also will investigate whether the textured insole positioned in the shoe on the non-affected side of stroke survivors could improve the symmetry of their stance and gait.
Chapter 2. Effect of a Textured Insole on Balance and Gait in Healthy Individuals.

2.0 Preview

According to the research by Aruin 13, the textured insole could alter symmetry in many aspects. Therefore, this study is a mimic of previous research.

2.1 Aim of the study

The aim of the study is to evaluate if the newly re-designed textured insole (T-insole) could create asymmetrical stance and gait in healthy individuals.

2.2 Method

Subjects:

8 healthy young individuals (age: 21-32, Male: 4, Female: 4) voluntarily participated in this study. The study was approved by the UIC IRB. The subjects were fully informed about the goals of the study and consented to participate in the study.

Procedure:

The following equipment was used in this study: Balance Master® (NeuroCom International Inc., OR, USA) and GAITRite® systems (CIR Systems, Inc. Havertown, PA, USA). Balance Master® system was used to measure static balance of the subjects. GAITRite® system was utilized to measure gait parameters of each individual. Each subject was tested two times using both the Balance Master® system and GAITRite® system. First subjects were tested with no insole, then with the insole placed in the shoe on the left side.
Outcome measures:

Static Balance

The static balance of each individual was assessed using the Weight Bearing Test of Balance Master® system. The subjects were positioned on the top of the dual force plate of the Balance Master according to the manufacturer’s guidance and the distribution of their body weight (as a percentage of the total body weight) between the left and right foot was measured.

Then, we calculated a Symmetry Index (SI) using the following equation:

\[ SI = 2 \times \frac{(V_{\text{contralateral}} - V_{\text{target}})}{(V_{\text{contralateral}} + V_{\text{target}})} \times 100 \]

\( V_{\text{target}} \) is the corresponding variable of the insole (target) side, in our case, the left side; \( V_{\text{contralateral}} \) is the corresponding variable of the no insole (contralateral) side (right side in our case). When SI equals 0, it means the left and right sides are in perfect symmetry. If the SI is positive, it means the variable on the contralateral side is larger than on the target side, and vice versa. A higher value of the SI reflects more asymmetry. Therefore, all the SI was standardized by the absolute value.

Gait

Gait parameters were captured by the GAITRite® system. The duration of stance phase, single support phase, and double support phase was calculated into the percentage of a gait cycle by GAITRite® software. SI indexes were calculated using the equation presented above.

Analysis:

Paired t-tests were applied to evaluate the difference between the two conditions: baseline and the use of an insole. The significance level was set at \( p < \)
0.05. Statistical analysis was performed by SPSS v.20 for Mac (SPSS Inc. Chicago, IL).

2.3 Results

Static Balance

Percentages of the body weight on the left and right side were calculated during the tests performed while standing with or without the T-insole. The SI index calculated during standing with no insole was 13.125 ± 10.125. (Figure 1). When standing with T-insole, the SI increased to 25.718 ± 18.718. The difference between the no insole and insole conditions was not statistically significant \( (p = 0.232) \). However, there was a tendency of increase in SI of the WB test.

![Symmetry Index of WB](image)

Figure 1: The WB Symmetry Index measured for no insole condition (baseline) and when a T-insole was placed in the shoe on the left side. It is notable that the SI is higher in the insole condition \( (M=25.718, SE= 7.044) \). There is no statistical significance between these two conditions \( (p > 0.05) \).
A number of gait parameters were affected by using the T-insole. Below we present the data on gait velocity, stance phase, single phase, and double support phase (Table 1).

**Gait velocity**

Average velocity in the baseline condition of healthy individuals was $141.906 \pm 22.254$ cm/sec. After applying T-insole, the velocity decreased to $131.663 \pm 21.599$ cm/sec. The difference between these two conditions was statistically significant ($t = 3.725, p < 0.05$). (Figure 2)

**Table 1: Gait parameters, Mean ± SD are shown**

<table>
<thead>
<tr>
<th></th>
<th>No Insole</th>
<th>Insole</th>
<th>$t$</th>
<th>Significance (p value)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Velocity</strong></td>
<td>$141.906 \pm 22.254$</td>
<td>$131.663 \pm 21.599$</td>
<td>$3.725$</td>
<td>$p &lt; 0.05$</td>
</tr>
<tr>
<td><strong>SI of Stance phase</strong></td>
<td>$1.974 \pm 1.693$</td>
<td>$4.710 \pm 2.482$</td>
<td>$-3.149$</td>
<td>$p &lt; 0.05$</td>
</tr>
<tr>
<td><strong>SI of single support phase</strong></td>
<td>$2.712 \pm 2.830$</td>
<td>$8.484 \pm 5.184$</td>
<td>$-2.690$</td>
<td>$p &lt; 0.05$</td>
</tr>
<tr>
<td><strong>SI of double support phase</strong></td>
<td>$3.605 \pm 4.260$</td>
<td>$7.414 \pm 6.827$</td>
<td>$-2.514$</td>
<td>$p &lt; 0.05$</td>
</tr>
</tbody>
</table>

**Figure 2:** Gait velocity measured by the GAITRite® system is shown for the two experimental conditions: with no insole (Baseline) and with insole (Insole).
**Stance phase**

The mean symmetry index for the percentage of the stance phase of a gait cycle in the baseline condition was $1.974 \pm 1.693$, while the SI of stance phase in the insole condition increased to $4.710 \pm 2.482$. The difference between these two conditions was statistically significant ($t = -3.149, p < 0.05$). (Figure 3)

![SI of Stance Phase](image)

*Figure 3: The symmetry index calculated for the stance phase of gait cycle for the experimental conditions with no insole (Baseline) and with insole (Insole).*

**Single support phase**

The mean SI for the single support phase of a gait cycle in the baseline condition was $2.712 \pm 2.830$, and the SI in the insole condition increased to $8.484 \pm 5.184$. The difference between these two conditions was statistically significant ($t = -2.690, p < 0.05$). (Figure 4)
Double support phase

The double support phase of a gait cycle was also measured and calculated into SI. The SI calculated for the double support phase in the baseline condition was $3.605 \pm 4.260$. When an insole was provided, the SI of the double support phase increased reaching $7.414 \pm 6.829$. The difference between the two conditions was statistically significant ($t = -2.514, p < 0.05$). (Figure 5)
Figure 5: The symmetry index calculated for the double support phase of a gait cycle while walking with no insole (baseline) and with insole (insole).

2.4 Discussion and Conclusions

All subjects were able to complete the tests. The use of the T-insole affected their static balance and gait.

Static Balance

While standing with the insole in the shoe on the left side, all study participants shifted their body weight towards their right side, thus inducing the body asymmetry. The induced asymmetry of stance is reflected in the increased SI indexes calculated using the data from the WB test. Thus, the SI index in the baseline condition was 13.125; in the insole condition it increased to 25.718. Since the smaller SI indexes refer to better symmetry\textsuperscript{38,39} the outcome of the study indicates that the use of the T-insole was associated with the worsening of the symmetry of stance in young healthy individuals. While the difference in the SI indexes between the two
experimental conditions was not statistically significant \( p = 0.232 \), the negative effect of the T-insole on the weight bearing symmetry could be observed (Fig. 2). The previous study conducted by Aruin et al.\textsuperscript{13} showed that the static balance has been altered in healthy individuals provided with a textured insole. Moreover, it was shown in that research, that subjects always shifted their weight to the no insole side as they tried to avoid discomfort induced by the insole. The results of the current study support the findings of the previous one. However, while similar to the previous trend in body weight shift was observed, the differences between conditions were not statistically significant. The reasons for a lack of statistical significance could be associated with: 1) small sample size. 2) short duration of the test so some subjects (based on their feedback) tried to resist the effect of the insole during the test and only after it was over (a few minutes after they wore the T-insole), complained about the discomfort. Yet, the increase of the SI on WB test could still be interpreted as an increase in the asymmetry of weight distribution.

\textit{Gait}

Based on the manual of the GAITRite\textsuperscript{®} system, the stance phase of a gait cycle is the weight bearing portion of a gait cycle \textsuperscript{40}. The stance of one limb includes double support and single support of the same side. The single support phase of the same side indicates the full body weight is placed on that side. The single support phase of one side is also a mirror value of the swing phase of the contralateral side. Double support could be divided into two parts: initial double support and terminal double support. Using right foot double support as an example, the initial double support phase of the
right foot is when the heel contact of the right foot occurs while the left foot is about to initiate the left foot swing phase. The terminal double support of the right foot is a part of the gait cycle from the left footfall heel strike to the right footfall toe-off. In this study, we refer the measurement of the double support as the total double support, which is the combination of the initial and terminal double support.

Gait velocity

Given that an insole could affect gait velocity, it was important to evaluate how the use of the insole inducing discomfort would affect gait velocity of healthy individuals. The prediction of this study was that when a subject was using the T-insole, the velocity would decrease due to the induced discomfort. The result showed that without the insole, the subjects could walk faster (Velocity = 141.906 cm/sec) than in the insole condition (Velocity = 131.663). There was a significant difference between magnitudes of gait velocity measured in these two conditions ($p < 0.05$). The observed decrease in gait velocity also seen in conditions with induced discomfort by rigid ankle-foot orthoses (AFO) which was described in the literature. It is important to note that the negative effect of the T-insole was observed only in healthy individuals whose gait velocity was normal to begin with. Future studies are needed to evaluate the effect of T-insole on gait velocity of individuals with impaired gait.

Symmetry indexes

Symmetry indexes calculated for the stance phase, single support phase, and double support phase of gait all increased in conditions with the T-
insole. The increased SIs indicate that the symmetry of phases of gait was diminished in healthy individuals. This could be explained that the T-insole induced discomfort. The results are similar with the outcome of the previous research of Aruin et al., which showed that when the insole was placed under the left or right foot of healthy individuals, there was a redistribution of the gait measures reflecting the induced asymmetry. To further investigate which part of the stance phase was affected by the T-insole, the analysis of the SIs for the single support phase and double support phase was conducted. The increase of SI of single support in the insole condition (Baseline = 2.712; Insole = 8.484) could be translated as the increase of asymmetry in single support phase when using the T-insole. The SI double support of a gait cycle was also increased in the insole condition (Insole condition = 7.414) compared with the baseline condition (Baseline condition = 3.605). Therefore, the use of the T-insole created a condition where the subjects showed larger asymmetries than in the baseline condition.

To sum up, the results of the study suggest that when subjects were provided with the T-insole, they tended to have more unstable gait patterns than when walking without the T-insole.
Chapter 3. Effect of Textured Insole on Balance and Gait in Post-Stroke Group.

3.1 Aims of the study

According to the previous research by Aruin\textsuperscript{13} and Chapter 2, the T-insole did affect the healthy individuals by creating static balance and gait pattern asymmetry as compared with the no insole condition. Thus, we demonstrated that the discomfort inducing textured insole (T-insole) could alter symmetry of static balance and gait in healthy individuals. However, even if the T-insole was proven to be effective on healthy individuals, it was not meant to be effective on people with neurological diseases. Therefore, the aim of this second study is to test if the T-insole could improve the symmetry on chronic stroke population.

3.2 Methods

Based on a previous study by Aruin\textsuperscript{13}, the original textured insoles were applied to the chronic stroke group.

Subjects:

8 subjects were recruited in this study (age: 43 - 66, male: 4; female: 4). The subjects signed the consent form approved by the UIC IRB. The basic demographic information is listed in Table 2.

The inclusion criteria were: a) subjects with hemiplegia resulting from a single onset of stroke; b) subjects did not undergo surgeries in the past 6 months that might affect their balance control and gait; c) subjects did not have other neurological disorders; d) subjects did not have cardiovascular or pulmonary
complications other than hypertension; e) subjects did not experience physical pain; f) subjects did not have orthopedic complications, such as osteoarthritis; g) subjects did not have lesions, ulcers, or skin damages at the bottom of feet; h) subjects could stand independently for 2 minutes without using walkers/canes; i) subjects could walk independently for 10 meters without using walkers/canes; j) the gait patterns of the subjects did not overlap on the ipsilateral side.

Table 2: Basic Demographic Information

<table>
<thead>
<tr>
<th>Age (years old)</th>
<th>Male</th>
<th>Female</th>
<th>Year of Post-Stroke (years)</th>
<th>Right Hemiparesis</th>
<th>Left Hemiparesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>45-66</td>
<td>4</td>
<td>4</td>
<td>2-15</td>
<td>5</td>
<td>3</td>
</tr>
</tbody>
</table>

Procedure:

Two pieces of equipment were used to collect the data: the Balance Master® (NeuroCom International Inc., OR) and GAITRite® systems (CIR Systems, Inc. Havertown, PA, USA). The Balance Master® was used to evaluate the static balance of each subject. The GAITRite® system was used to measure gait parameters. First, the subjects were asked to stand on the Balance Master® for the Weight Bearing test. Then, the subjects were asked to walk on the GAITRite® walkway three times to record baseline gait parameters. After the baseline data were collected, the subjects were asked to place a T-insole in the shoe on the less-affected side. Then, the subjects were tested again using the Balance Master® and GAITRite®.

Outcome Measures:

Static Balance

Static Balance was tested using a weight bearing test of the Balance Master® system. The weight bearing test shows how much weight each subject applied on the left or right side of the body. Symmetry index (SI) was calculated
by Robinson’s equation $^{38}$ using the percentage of the body weight applied on each side separately for the baseline and insole conditions.

**Gait**

Gait parameters were collected by the GAITRite® system. Velocity, stance phase, single support phase, and double support phase of a gait cycle were calculated by GAITRite® software. SI was calculated by Robinson’s equation with absolute value. According to Shumway-Cook$^{42}$ stance phase is the weight-bearing portion of a gait cycle. It initiates at heel contact and terminates with toe-off of the same foot. Single support phase is the period when only one foot is in contact with the ground and bears all the weight. Single support phase is also a mirror representation of the swing phase of the contralateral foot (Figure 6). Double support phase could be divided into two parts: initial double support and terminal double support. Initial double support occurs from heel contact with one footfall to toe-off of the opposite footfall. Terminal double support occurs from heel strike of the opposite footfall to toe-off of one foot. The total double support phases were calculated by the GAITRite® software. Gait velocity was normalized by the baseline value.

![Figure 6: Different Phases of a Gait Cycle](image)
**Analysis:**

Paired t-test was applied to evaluate the difference between the two conditions: baseline and the use of insole. The significance level was set at $p<0.05$. Statistic analysis was performed by the SPSS software v.20 for Mac (SPSS Inc. Chicago, IL).

### 3.3 Results

**Static Balance**

When subjects were asked to stand on the Balance Master® without the T-insole, the SI was $39.000 \pm 11.008$. When the subjects were asked to wear the T-insole, the SI improved reaching $20.585 \pm 11.646$. While the effect of the T-insole was seen (Figure 7), the difference between these two conditions was not statistically significant ($p = 0.232$).

![SI of Weight Bearing](image)

**Figure 7:** The Symmetry Index of WB indicates that the SI is lower in the insole condition.
Gait

Because all the subjects were individuals with chronic stroke, the velocity differs from one to the other. Thus, normalization is needed for one's baseline condition. Before calculating the normalized data, the mean of the velocity of gait in the baseline condition was 50.473 ± 21.645 (cm/sec), and in the insole condition, the mean velocity was 47.974 ± 23.038 (cm/sec). (Figure 8) For the baseline condition, the normalized velocity was 1.000 ± 0.000, and in the insole condition, the normalized velocity was 0.940 ± 0.842. While in conditions with the T-insole the velocity slightly decreased (Figure 9); the paired t-test revealed that the difference between the two conditions was not statistically significant ($p = 0.082$).

![Gait Velocity](image)

**Figure 8: Gait Velocity measured by GAITRite® system**
Figure 9: Normalized gait Velocity measured by the GAITRite® system.

For the stance phase of gait cycle without wearing T-insole, the mean of SI in the baseline condition was 26.703 ± 11.077. In the insole condition, the mean of SI of stance phase was 19.791 ± 8.613. The difference for the stance phase between conditions was statistically significant ($t = 3.214, p < 0.05$). (Figure 10)

Figure 10: The symmetry index of the Stance phase of a gait cycle.
The mean of SI of single support phase in the baseline condition was 60.020 ± 26.337, while the mean of SI of the single support phase in the insole condition decreased to 45.451 ± 22.687. There were statistically significant differences between these two conditions ($t = 4.075, p < 0.05$). (Figure 11)

![SI of Single Support Phase](image)

**Figure 11: The symmetry index of single support phase of a gait cycle.**

The SI was also calculated for the double support phase of a gait cycle. The SI of the double support in the baseline condition was 1.322 ± 1.828, and the SI of the double support in the insole condition was 2.190 ± 1.708. The difference between the SI in the baseline condition and in the insole condition was
statistically significant \( (t = -2.570, p < 0.05) \). (Figure 12) All the gait parameters were organized in Table 3.

![SI of Double Support Phase](Figure 12: The symmetry index of a double support phase of a gait cycle.

Table 3: Gait parameters, Mean ± SD are shown.

<table>
<thead>
<tr>
<th></th>
<th>No Insole</th>
<th>Insole</th>
<th>( t )</th>
<th>Significance (( p ) value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Velocity</td>
<td>50.473 ± 21.645</td>
<td>47.974 ± 23.038</td>
<td>1.667</td>
<td>( p = 0.139 )</td>
</tr>
<tr>
<td>SI of Stance phase</td>
<td>26.703 ± 11.077</td>
<td>19.791 ± 8.613</td>
<td>3.214</td>
<td>( p &lt; 0.05 )</td>
</tr>
<tr>
<td>SI of single support phase</td>
<td>60.020 ± 26.337</td>
<td>45.451 ± 22.687</td>
<td>4.075</td>
<td>( p &lt; 0.05 )</td>
</tr>
<tr>
<td>SI of double support phase</td>
<td>1.322 ± 1.828</td>
<td>2.189 ± 1.708</td>
<td>-2.570</td>
<td>( p &lt; 0.05 )</td>
</tr>
</tbody>
</table>

### 3.4 Discussion and Conclusions

**Static Balance**

The effect of the T-insole on the body weight bearing redistribution was confirmed by the decreased SI index. The average SI decreased 4.707% on the insole side in the conditions with the T-insole compared to the baseline condition. The SI of WB decreased by 18.415 in the insole condition. However,
the difference between the baseline and insole conditions was not statistically significant. However, the tendency of decrease in SI could still be interpreted as the insole-related improvement of symmetry of weight bearing in individuals with stroke.

Gait

The results of research on plantar fasciitis and gait pattern show that the painful sensation would lead to decrease of the gait velocity\textsuperscript{43}. Similarly, since the T-insole induces discomfort, gait velocity was expected to decrease due to the discomfort sensation. However, the result showed that the decrease was minor regardless of the induced discomfort (Normalized Velocity in the baseline condition: 1.000, in the insole condition: 0.940). It is important to note that 2 out of 8 subjects increased their walking speed while using the T-insole. This phenomenon might be due to different strategies each individual used to deal with the insole condition. Nevertheless, the small change of the gait velocity is a positive outcome as it tells us that the gait itself did not change a lot between the experimental conditions with and without the T-insole. The goal of this study was to prove that the T-insole could improve stance and gait symmetry in individuals with chronic stroke. The results of this study suggest that it was indeed the case. In addition, we wanted to explore whether the new T-insole could be used by patients for longer periods of time. The outcome of the study revealed that while individuals with stroke improved their symmetry of stance and gait in condition with the T-insole, their gait velocity was not jeopardized.

For the stance phase, the decrease of SI in the insole condition (Baseline condition: 26.703, insole condition: 19.791) could be interpreted as an improvement in gait symmetry. The result could be explained that the T-insole
induced discomfort sensation to the less-affected side, which encouraged the subjects to shift their body weight to the more-affected side. Moreover, the SI of the single support phase also decreased (baseline condition: 60.020, insole condition: 45.451), which proved that when subjects were using T-insole the weight distribution during gait was more symmetrical than during the walking with no insole. However, the SI of double support phase increased in the insole condition (Baseline condition: 1.322, insole condition: 2.190). This might be because the termination of a step on the insole side and the termination of a step on the more-affected side became prolonged due to the user’s hesitation from using the more-affected side to bear more weight than in their usual gait pattern. However, the exact reasons for the observed differences need to be examined further.

In summary, based on the results of the analysis of gait parameters, the application of a T-insole in the individuals with chronic stroke did improve the symmetry of their gait pattern compared with their usual walking pattern.
Chapter 4. Effect of Different Textured Insoles on Balance and Gait in Healthy Individuals.

4.0 Introduction

Experiments described in Chapter 2 focused on how the T-insole would affect healthy individuals’ static balance and gait. The results showed that the T-insole could be an effective tool in changing symmetry of stance and gait as healthy individuals with no asymmetries worsened their static balance and gait pattern while using a T-insole. Moreover, the study described in Chapter 3 proved that the T-insole could improve the symmetry of static balance and gait patterns in individuals with chronic stroke. However, the experiments described in Chapters 2 and 3 were based on using one type of the T-insole.

4.1 Aims of the study

After performing the previous two studies, the next question was: “What type of the T-insole could patients use daily?” Moreover, the effect of using the T-insole for a relatively longer period of time was not tested in the previous two studies. Therefore, the goal of this study was to compare three different prototypes of the T-insoles. We wanted to assess the performance of subjects using each insole prototype to find out which one is more suitable to the general public. Another aim of this study was to investigate the effect of the longer usage of the T-insole.
4.2 Methods

There were over 10 different prototypes designed in cooperation with the UIC Innovation Center and tested in pilot trials. The goal of the pilot trials was to find out whether it is realistic to conduct the more extensive tests using a particular type of the T-insole or more modifications to the insole design are needed before testing the prototype. Based on the outcomes of these pilot tests, we narrowed down the number of prototypes to 3. It is important to mention that other prototypes were not rejected; they just needed more detailed adjustments before moving to the full-scale tests. The three selected prototypes were 1) the re-aligned projection-layout insole (whole insole), 2) the thin foam with re-aligned projection-layout insole (thin foam insole), and 3) thick foam with re-aligned projection-layout insole (thick foam insole).

Subjects:

8 young individuals (age: 21-32, male: 4, female: 4) voluntarily participated in this study. Participants had no neurological or musculoskeletal deficits. The subjects were fully informed and consented to participate in the study.

Procedure:

Since there were three different prototypes, the subjects were asked to come and participate in the experiments on four different days (one extra day for baseline testing). Each day, the subjects had to perform the following procedure. The subjects were first asked to wear their own comfortable shoes to do the baseline testing on the Balance Master® and GAITRite® systems for static balance and gait parameters (Detailed description of the tests is presented in Chapters 2 and 3). Then, the subjects were required to place one prototype in the
shoe on the left side. Then subjects were provided with a 1-minute break to adjust to the insole before continuing the following tests. Afterwards, the subjects were asked to perform a 12-minute walking test. The 12-minute walking test was divided into 3 periods: 5 minutes, 5 minutes, and 2 minutes. The subjects were required to walk continuously during these three periods of time, but in between the three periods of time, subjects were asked to walk on the GAITRite® walkway and stand on the Balance Master® platform for measuring the static balance and gait patterns. After the 12-minute walking test was completed, participants were asked to take out the insole and rest for 5 minutes with their shoes on. After 5 minutes of rest, the subjects were required to perform the same tests to evaluate the post-effect of the insole on their balance and gait. At each testing time point, the subjects were required to use the visual analog scale for self-grading discomfort. The schematic order of the tests is shown in Figure 13.

Figure 13: Procedure for testing the effect of the three prototypes.
Outcome measures:

Static Balance

The evaluation of static balance was performed using the Balance Master® system. The result represented the percentage of one’s weight distribution between the left and right feet in quiet standing condition. The percentage of the body weight was used to calculate Robinson's symmetry index 38 which was to identify which prototype is associated with more asymmetrical static balance pattern.

Gait

The gait parameters were collected by the GAITRite® system. Velocity, stance phase, single support phase, and double support phase of a gait cycle were used to evaluate one's gait pattern. SI of different parameters was calculated by Robinson’s equation 38.

Visual Analog Scale (VAS)

Since the selected prototype could be considered for future mass production, it was important to receive the user's feedback reflecting their subjective feeling. The visual analog scale was a self-assessed scale; it was previously used in various research 44-46. Therefore, we utilized the VAS for self-assessment; we consider VAS outcome a crucial measure for future improvements of the prototypes. The VAS is a simple tool that is often used for evaluation of pain level. The subjects were asked to make a mark on a 10 cm line, in which one end of the line is marked as “no discomfort at all” while the other end is marked as “worst discomfort ever”. The outcome of this test, presented as a percentage (from 0% to 100%) was used to reveal the discomfort level.
Statistics:

The data were calculated by factorial ANOVA using the SPSS software. Since the main focus of this study was how different prototypes affect tests, thus, the accumulating values from different time points were treated equally in terms of testing for different tests, which means the time-effects were negligible when evaluating the difference.

4.3 Results

All subjects were able to complete the tests. The text below describes the outcome of the study related to the investigation of the effect of the three prototypes of the T-insole in creating the largest effect on the asymmetry of static balance and gait.

Static Balance

To compare which prototype could affect the static balance, the Balance Master® was used to collect the data and compute the symmetry index according to Robinson’s equation. However, based on the results, the values of the SI were not significantly different between the tests involving the three prototypes and a no insole condition. However, while there was no statistical significance ($p = 0.061$), the SI calculated for the thick foam type ($M=4.75$) and no insole condition ($M=7.625$) were smaller (indicating better in symmetry level) than the SI for the thin foam ($M=14.625$) and whole insole prototypes ($M=14.063$). (Figure 14)
Gait parameters were collected several times throughout this study. The reason was to see if there would be a time-effect in different prototypes. However, to deal with the key question: “Which prototype created the greatest effect on different tests?” the time-effect would not be the primary concern. Thus, the data were simplified according to the main research question. For velocity, the four prototypes were significantly different from each other ($F_{(3,128)} = 3.861, p < .05$). Tukey’s HSD showed that the baseline condition (Mean = 133.825 cm/sec) and thick foam condition (Mean = 132.914 cm/sec) had significantly higher magnitudes of gait velocity than the whole insole condition (Mean = 119.673 cm/sec), $p < 0.05$ (Figure 15).
Figure 15: Gait velocity changes while walking using different prototypes of the T-insole. Statistical significance between the prototypes (p < 0.05) is shown with *.

For the SI of the stance phase, the four prototypes were significantly different from each other ($F_{(3,128)} = 4.004, p < .05$). Tukey’s HSD showed that the SI for the thick foam condition (Mean=-1.126) was significantly lower than the SI for the whole insole condition (Mean=1.785), p <0.05. (Figure 16)

Figure 16: Symmetry Index of the Stance phase. Statistical significance between the prototypes ($p<0.05$) is shown with *.

For the SI of the single support phase, the four prototypes were significantly different from each other ($F_{(3,128)} = 3.953, p < .05$). Tukey’s HSD
showed that the thick foam condition (Mean=-3.376) had significantly lower SI indexes than the whole insole condition (Mean=3.708), $p < 0.05$. (Figure 17)

### Symmetry Index of Single Support Phase

![Symmetry Index of Single Support Phase](image)

**Figure 17:** Symmetry Index of the Single support phase. Statistical significance between the prototypes ($p < 0.05$) is shown with *.

For the SI of the double support phase, there was no significant difference between the four prototypes ($F(3, 128)=1.148, p = 0.333, ns$). (Figure 18)

### Symmetry Index of Double Support Phase

![Symmetry Index of Double Support Phase](image)

**Figure 18:** Symmetry Index of the Double support phase.
**Visual Analog Scale**

Visual analog scale (VAS) was used to evaluate the subject's subjective discomfort associated with using a T-insole. The VAS tests revealed that there were statistically significant differences between the prototypes ($F_{(3,12)} = 15.137$, $p < 0.05$). Tukey’s HSD showed that the VAS of the whole insole prototype (Mean=44.705%) was significantly higher than all other three prototypes (no-insole condition: $M = 0.262\%$, thin foam prototype: Mean= 15.704, thick foam prototype: Mean= 15.068), $p < 0.05$ (Figure 19).

**VAS of Discomfort Level**

![VAS of Discomfort Level Diagram]

Figure 19: Discomfort level measured with the Visual Analog Scale. Statistical significance between the prototypes ($p < 0.05$) is shown with *.
4.4 Discussion and Conclusions

Static Balance

Based on the results presented in the previous two chapters, the aim of this study was focused on the evaluation of the effect of different prototypes of the T-insole. The hypothesis was that the use of the T-insole would alter the weight distribution of the participants resulting in the increase of the symmetry index. However, the results related to the weight distribution between the two feet were not significantly different between the conditions involving wearing different prototypes of the T-insole. Yet, while not significant, there was a trend ($p = 0.061$) that the thin foam and whole insole were more effective in creating weight-bearing asymmetry than the no insole condition and thick foam insole. It is important to mention that the design of the protrusions in the whole insole and thin foam prototypes were relatively similar which might explain the similarity between the effects of the two insoles. On the other hand, the thick foam prototype performed better than no insole, which might be due to the material used in the thick insole that could compress under the load and create a more stable sensation to the subject, which might lead to more symmetry than in the no insole condition. Recent literature describing that a compressed material of the insole could improve the balance and symmetry of weight distribution supports the finding related to the relatively small effect of the thick foam in creating the asymmetry of stance.
Gait

According to the results, the changes in velocity, stance phase, and single support phase of a gait cycle were all statistically significant between the conditions of wearing different prototypes. However, post hoc analysis showed that only the whole insole was significantly different from the thick foam prototype. This could be explained by the possibility that the whole insole prototype creates a larger feeling of discomfort and as such is more effective than the thick foam one. In addition, since the thick foam prototype results were close to the other two types, the whole insole prototype was considered as the most effective type in changing gait symmetry. This result revealed that projections of a larger magnitude could induce more discomfort sensation, which would create more gait symmetry. Thus, with the whole insole, the velocity decreased, and changes in the stance phase showed that the subjects leaned toward the no insole side, and during the single support phase they leaned toward the no insole side. However, with different prototype types such as thin and thick foam, gait velocity was close to the velocity measured during walking with no insole. There was a tendency in the stance and single support phase of a gait cycle while walking using the thin and thick foam prototypes that the subjects tended to lean on the insole side. This might be due to a positive reinforcement, similar to one described by Christovão 31, which could enhance the balance due to the pressure absorption insole. However, the mechanism of such a positive reinforcement is still unclear and needs further research. The changes in the double support phase associated with these four different types of insoles were minor, and they do not support the outcomes of the previous study.
However, the reason behind the observed minor change in the SI during the double support phase might need further investigation.

*Visual Analog Scale*

The results demonstrated that the whole insole prototype created more discomfort sensation than other conditions. This study outcome could be explained that with relatively higher dimensions of the projections, the whole insole induced more stimuli than others. However, this could also jeopardize the expected goal for this study, which is to have the insole provided to individuals with chronic stroke daily: the insole with higher discomfort level might decrease the motivation related to wearing this type of the insole.

The outcomes of the VAS tests led to another question related to how to rank different insoles? The three different prototypes were able to create a certain effect on the static balance and gait parameters. However, not all of the studied prototypes created changes in the symmetry of stance and gait that were reported previously in Chapters 2 and 3. This might be due to the different design and strategies that one might use to compensate for the intervention involving discomfort. So far, based on the results described in this chapter, the whole insole prototype created the most effect on static balance and gait parameters. The thick insole created more positive reinforcement than others and this was not expected before the study was launched.
Chapter 5. Summary

The goal of this series of studies was to understand if the T-insole could benefit individuals with stroke in improving symmetry of stance and gait.

Therefore, in Chapter 2, the study was conducted to understand if the novel T-insole would alter symmetry of gait and stance in healthy individuals. The results showed that the gait parameters were altered and asymmetry was seen in healthy individuals when the participants were wearing the T-insole. This result supports the hypothesis that the T-insole could affect the gait pattern in healthy individuals.

Chapter 3 targeted individuals with chronic stroke. Since Chapter 2 already proved that the T-insole could alter the gait parameters, the next logical step was to test if the T-insole could benefit individuals with stroke. The results showed that the immediate effect of the T-insole was not seen in stance balance as there was no statistically significant improvement in the weight bearing distribution between the conditions with and without standing with the T-insole. However, the use of T-insole was proven to improve the gait symmetry in individuals with stroke. Although the previous two chapters revealed changes in different parameters, the outcomes of these two experiments did not provide a clarification about what kind of design would be most effective in improving the balance.

Thus, the third experiment described in Chapter 4 was conducted to find out which T-insole design produces more changes to balance and gait parameters in healthy individuals. The results revealed that the weight-bearing stance was not changed significantly due to the use of different prototypes.
However, there were some significant changes in gait velocity, symmetry of stance phase, and single support phase of a gait cycle between conditions of using different T-insole prototypes. The results also revealed that there was one insole prototype that was most effective in altering the gait pattern in healthy individuals. This T-insole prototype will be used in future experiments involving individuals with stroke.

These studies were designed coherently to demonstrate that the novel type of the assistive device would benefit individuals with stroke. The results supported the hypothesis but only partially. The studies included in the thesis could be considered as preliminary. Future studies are needed to provide additional information related to the use of discomfort-inducing insoles in rehabilitation of individuals with stroke.

There are a number of limitations that we would like to report. First, the sample size in each experiment was small, as there were only 8 subjects in each of the healthy groups and in the stroke population. The sample size affected the power of the studies. Thus, it is important to recruit more subjects to be able to demonstrate more statistically significant results in future research.

Second, a lack of significant results in the study involving individuals with stroke (Chapter 3) could also be due to the stroke-related sensory decline. In the research of Kim et al., the researchers found that in individuals with unilateral stroke, the discriminative sensory ability would still be affected bilaterally. Based on the research of Nelles et al. and Chen et al., the somatosensory and motor functions were affected by stroke. Therefore, the limited changes in stance balance and gait due to the use of the T-insole described in Chapter 3 might be due to the decline of somatosensory sensation after stroke. If it is indeed the case,
a T-insole with larger protrusions (that create larger effect) should be considered as an alternative approach in dealing with the diminished somatosensory threshold in the individuals with stroke. In addition, the sensory threshold of the study participants was not assessed in the current study that could also be considered as a study limitation.

Despite the described limitations, the studies described in Chapters 2, 3, and 4 provide important pilot data that could be used while planning for future experiments focused on establishing the efficacy of the T-insole. These future studies should include measuring some other clinical outcomes as well as to involve more detailed analysis of gait of individuals with stroke using motion analysis and EMG systems.

**Acknowledgements**

The author wishes to thank the advisor, Professor A.S. Aruin. Special thanks to the members of the Harry G. Knecht Movement Science Laboratory: Y. Lee, M. Ganesan, B. Chen, S. Jagdhane, and S. Olidare. This study was conducted in cooperation with the UIC Innovation Center. It is equally important to thank S. Muthukrishnan MD for help in recruiting subjects.

The study was in part supported by the grant from the American Heart Association (AHA) and the UIC Chancellor’s Proof of Concept (POC) grant (PI Dr. A. Aruin).
References:


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