Effectiveness of Evenup™ Shoe-Lift Use Among Individuals Prescribed a Walking Boot

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BACKGROUND: Walking boots are prescribed after foot and ankle injuries, allowing immediate ambulation for patients. However, temporary limb-length inequality (LLI) may result, causing dysfunction and pain, including low back pain. The Evenup™ shoe-lift was designed to eliminate joint pathology, pain, and gait deviations resulting from walking-boot-induced LLI, yet no clinical trials have been reported on its effectiveness. METHODS: Thirty-four subjects undergoing unilateral lower-extremity orthopedic medical and rehabilitative care were recruited for this study. Seventeen subjects were assigned to an intervention group using a walking boot on the foot of their involved side and the Evenup™ on the other foot, while the control group used a walking boot only on the involved side. Outcome measures included the lower extremity functional scale (LEFS), modified Oswestry low back pain disability questionnaire (OSW), numeric pain rating scale, ankle range of motion (ROM) and strength. RESULTS: All subjects, regardless of the intervention, demonstrated improved function, decreased pain, increased ROM, and increased strength. Additionally, a clinically relevant difference was found between the intervention and control groups for the OSW and LEFS. CONCLUSION: LEFS and OSW results suggest Evenup™ use added value in the form of improved patient function. J Allied Health 2017; 46(2):104–110.

A WALKING BOOT is commonly prescribed following an ankle, foot, or lower leg injury to keep the patient as mobile as possible while minimizing pain and swelling. The boot is typically worn for 6 to 8 weeks following fractures and ankle sprains, and for up to 12 weeks following surgery such as Achilles tendon repair. It protects the injured structure by limiting ankle motion. However, the thickness of the boot sole, reported to be as great as 5 cm,²² causes a discrepancy between leg lengths,²⁸ with the potential to cause pain and dysfunction in other joints.

Lower-limb inequality (LLI) has been associated with numerous joint pathologies including those of the hip,¹²,²⁴ knee,¹³ ankle/foot complex,¹⁷ temporomandibular joint (TMJ),¹⁵ sacroiliac,¹⁴ and spine,¹³,²⁵–²⁷ including idiopathic scoliosis.¹¹,¹³,¹⁹,¹⁵ Rannisto et al.,²² using a reliable ultrasound method to measure for LLI in 114 meat-pickers, found a 6-mm discrepancy or more was associated with higher intensity and number of days with low back pain. Though the exact mechanism of LLI-induced low back pain was unclear, the researchers of this study suggested that asymmetrical lower extremity loading during walking causes abnormal stress in the pelvis and lumbar spine. Defrin et al.⁵ suggested the pathomechanics of LLI-induced low back pain to be pelvic obliquity causing postural scoliosis and increasing the working load on muscles, ligaments, and joint capsules. The pain and dysfunction of other joints implicated with LLI could have similar biomechanical causes due to asymmetrical loading.

Common conservative management to equalize LLI focuses on shoe modifications to raise the short side (heel and full-length insert or external heel shoe-lift) or to trim the sole of the shoe on the longer side. Research conducted with individuals with chronic low back pain and LLI demonstrated increased lumbar spine motion and improved low back pain symptoms with the application of a heel-lift.⁵,⁸,¹⁰,¹¹

For short-term management of walking boot-induced LLI, use of a contralateral shoe-lift is available.¹⁶,¹³ The Evenup™ (Evenup Corp., Buford, GA) is an adjustable shoe-lift designed to be worn temporarily below the shoe of the non-involved foot to reduce joint pathology and gait deviations resulting from walking boot-induced LLI.⁶ Presently, only two investigations of the Evenup™ device have been reported. McDonald et al.¹⁸ studied 10 young healthy subjects (mean age 25 yrs) using an Evenup™ and walking boot in a gait laboratory. Seven of the 10 subjects reported greater comfort when wearing the Evenup™ compared to using the walking boot alone. Similarly, Crews et al.⁴ conducted an investigation of 25 individuals ambulating in short
and tall walking boots with and without the Evenup™. Using a visual analog scale, the subjects reported increased comfort when using the Evenup™.

The purpose of our study was to compare outcomes of pain, function, and ankle range of motion and strength of individuals using a walking boot for orthopedic conditions either with or without an Evenup™ (Table 1).

## Methods

The research design was a prospective experimentally controlled study of individuals with lower extremity orthopedic injuries wearing a walking boot with or without the use of an Evenup™ to correct the walking boot-induced LLI (Figure 1). Pain and dysfunction consequent to wearing a walking boot were compared between the two groups.

## Participants

Participants were recruited from persons consulting orthopedic surgeons at Southwest Michigan Center for Orthopaedics & Sports Medicine. A coin toss method was used to determine group assignment for the first subject. Individuals were informed about the study when the durable medical goods representative issued their walking boot. The researcher contacted the potential participants at the physician’s office or by phone within a day. Prior to participation, the purpose and procedures of the study were explained to each individual, and informed consent was obtained per the research protocol. The research protocol was approved by the Institutional Review Board of Andrews University.

Subjects were eligible to participate in this study if they were community-dwelling, 18 to 65 yrs of age, sustained an orthopedic injury to the ankle, foot, or leg, met the criteria for the prescription of a walking boot by an orthopedic surgeon, and allowed partial weight-bearing through the involved lower extremity. Subjects could use an assistive device such as a cane, crutches, or knee scooter.

Persons with leg, ankle, or foot injuries were excluded from the study if they were <18 or >65 yrs of age, lived at any type of assisted care facility, were prescribed bilateral walking boots, previously underwent spinal surgery, or had been diagnosed with a balance disorder, thoracolumbar scoliosis, or LLI. Subject attrition occurred due to changes in their insurance coverage or lack of insurance and choosing not to return for follow-up.

## Measures

Pre- and post-intervention self-reported outcome measures included the Lower Extremity Functional Scale (LEFS), modified Oswestry Low Back Pain Disability Questionnaire (OSW), and numeric pain rating scale (NPRS), and clinical measures of active range of motion (AROM) and manual muscle strength (MMS) tests.

### TABLE 1. Hypothesis Test Summary

<table>
<thead>
<tr>
<th>Null Hypothesis</th>
<th>Test</th>
<th>Exact significance is displayed for respective test(s) at a 0.05 significance level</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The distribution of post pain worst involved LE is the same across categories of treatment groups.</td>
<td>Independent samples Mann-Whitney U-test</td>
<td>0.634</td>
<td>Retain the null hypothesis</td>
</tr>
<tr>
<td>2. The distribution of post MMS test DF involved LE is the same across categories of treatment groups.</td>
<td>Independent samples Mann-Whitney U-test</td>
<td>0.760</td>
<td>Retain the null hypothesis</td>
</tr>
<tr>
<td>3. The distribution of post MMS test PF involved LE is the same across categories of treatment groups.</td>
<td>Independent samples Mann-Whitney U-test</td>
<td>0.474</td>
<td>Retain the null hypothesis</td>
</tr>
<tr>
<td>4. The distribution of post MMS Test INV involved LE is the same across categories of treatment groups.</td>
<td>Independent samples Mann-Whitney U-test</td>
<td>0.474</td>
<td>Retain the null hypothesis</td>
</tr>
<tr>
<td>5. The distribution of post MMS test EVN involved LE is the same across categories of treatment groups.</td>
<td>Independent samples Mann-Whitney U-test</td>
<td>0.919</td>
<td>Retain the null hypothesis</td>
</tr>
</tbody>
</table>

LE, lower extremity; DF, ankle dorsiflexion; PF, plantar flexion; INV, ankle inversion; EV, ankle eversion.
The LEFS comprises 20 items scored from 0 (unable) to 4 (no difficulty). Scores are summed to determine functional ability, with a maximum of 80 points possible. Binkley et al. found the LEFS demonstrated excellent test-retest reliability and required 9 points to achieve a minimal clinically important difference. The modified OSW is comprised of 10 questions, scored from 0 to 5, with a maximum of 50 points possible. Scores are summed and multiplied by two to calculate percentage of disability caused by pain from 0% to 100%. Fritz and Irrgang reported 6 points were required on the OSW for a minimal clinically important difference. The NPRS is an 11-point scale from 0 (pain free) to 10 (worst pain possible), reported to have a 2-point minimum clinical important difference for subjects with low back pain and various conditions.

### Procedures

Subjects were seated on a treatment table, and their ankle AROM was measured to the nearest degree with a standard 12-inch goniometer. Dorsiflexion, plantar flexion, inversion, and eversion were measured within the persons’ comfort tolerance if pain-free, or without any increased pain if the volunteer was already painful. A 0–5 scale for MMS was utilized as outlined by Kendall et al., unless contraindicated by post-traumatic acuity or post-operative protocol. If strength testing was contraindicated, a 0/5 was assigned to the muscles involved. Each subject was instructed in how to perform a home program including gentle ankle AROM and strengthening exercises, lower limb elevation, and use of modalities as clinically indicated. All individuals were asked to wear the walking boot on their involved lower extremity as prescribed by their physician. Subjects in the intervention group were also issued an Evenup™ and instructed in its proper use. All subjects were asked to record the number of hours per day they wore their medical device(s) in a wear time log.

### Sample Size and Statistical Analysis

Accounting for probable participant attrition, a priori sample size calculation estimated 40 participants would be needed (20 per group) to detect a between-group difference of 9 points in the final LEFS mean scores, considering a 16-point standard deviation (SD); an alpha level of 0.05, and power of 80%. Since the Evenup™ is a new device, a small effect size of 0.10 was deemed appropriate.

Data from this study were analyzed using SPSS Statistics, ver. 22 (SPSS Inc., Chicago, IL). A repeated measures ANOVA test with a significance level of 0.05 was used to analyze the group means from initial evaluation and discharge. An independent t-test was used to determine if there were any differences of outcomes between control and intervention groups. A Mann-Whitney U-test was performed to analyze results of MMS testing and pain reported between groups. After change scores of group means were calculated, a Spearman’s rho was performed to determine if correlations existed between Evenup™ use and outcomes.

### Results

Fifty-one subjects consented to participate in this study between June 2011 and May 2014. Thirteen data sets were incomplete, and so were deleted, leaving 38 usable data sets. Outliers who wore the walking boot <40 hrs, the Evenup™ only 1 hr, or attended physical therapy less than two times were excluded, leaving a sample of 34 complete data sets, with 17 subjects in each group (mean age ± SD, 43.4±13.8 yrs; females = 17, 50%). The mean number of hours subjects wore the walking boot was 463 (±439) for the control group and 334 (±265) for the Evenup™ group. Subjects in the intervention group also wore the Evenup™ a mean of 201 hrs (±126).

The sample size ended up lower than anticipated due to the following reasons. A lack of perceived incentive to participate may have contributed to the low recruitment number. A greater than expected subject dropout rate occurred. Also, the referring orthopedic group experienced several personnel changes, which influenced referral patterns to physical therapy including walking boot referrals.

### Self-Reported Measures

Table 2 provides pre- and post-test mean scores for the LEFS, OSW, and NPRS.

<table>
<thead>
<tr>
<th></th>
<th>Pre-LEFS (0–80)</th>
<th>Post-LEFS (0–80)</th>
<th>Pre-OSW (0–50)</th>
<th>Post-OSW (0–50)</th>
<th>Pre-NPRS (0–10)</th>
<th>Post-NPRS (0–10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evenup</td>
<td>28.82±15.10</td>
<td>63.29±10.83</td>
<td>15.41±10.54</td>
<td>3.47±4.84</td>
<td>8.53±1.97</td>
<td>2.65±2.60</td>
</tr>
<tr>
<td>Control</td>
<td>29.88±14.22</td>
<td>56.00±15.80</td>
<td>13.41±10.10</td>
<td>5.82±8.83</td>
<td>8.47±2.24</td>
<td>2.41±2.58</td>
</tr>
</tbody>
</table>

### Table 2. Group Means for Pre- and Post-Test Scores for Self-Reported Measures
lation between number of hours wearing the Evenup™ and LEFS change score: \(r=0.191, n=34, p=0.279\).

**OSW:** Repeated measures ANOVAs of OSW score group means showed subjects in both groups reported an improvement of functional status from pre- to post-test \((F=25.59, df=1.32, p=0.001; \text{Fig. 3A})\). There was not a statistically significant difference between OSW group means at discharge \((F=1.270, df=1.32, p=0.268; \text{Fig. 3B})\). Mean change score for the control was 7.59±12.64 and for the Evenup™ was 11.94±9.69 (Fig. 3C). No significant correlation was found between number of hours wearing the Evenup™ and OSW change score: \(r=0.149, n=34, p=0.401\).

**NPRS:** Repeated measures ANOVAs of mean NPRS scores showed the worst pain reported for both Evenup™ and control groups reduced significantly over time \((F=155.95, df=1.32, p=0.001)\) (Fig. 3A). A meaningful difference between post-group mean scores at discharge was not found \((F=0.34, df=1, 32, p=0.855)\) (Fig. 3B). A Mann-Whitney U-test of lower extremity pain reported at discharge revealed no difference between the Evenup™ (Md=18, n=17) and control group (Md=17, n=17); \(U=159, Z=0.491, p=0.634, r=0.08\) (Table 2). Mean change score for the control was 6.06±2.93 and for the Evenup™ was 5.88±2.64 (Fig. 3D). No significant correlation was found between number of hours wearing the Evenup™ and NPRS change score \((r=-0.056, n=34, p=0.752)\).

### Clinical Measures

**AROM:** Repeated measures ANOVAs showed that all subjects increased in dorsiflexion AROM from \(-9^\circ±10^\circ\) to \(3^\circ±5^\circ\) \((F=30.43, df=1, 32, p=0.001; \text{Fig. 4})\), yet there was no difference between group means at discharge \((F=0.187, df=1, 32, p=0.668; \text{Table 3})\). Both Evenup™ and control groups improved in plantar flexion AROM from \(48^\circ±12^\circ\) to \(61^\circ±11^\circ\) \((F=39.08, df=1, 32, p=0.001; \text{Fig. 4})\), but there was no difference between group means at discharge \((F=0.253, df=0, 32, p=0.618; \text{Table 3})\). Both groups improved in inversion AROM from \(15^\circ±10^\circ\) to \(22^\circ±7^\circ\) \((F=27.66, df=0, 32, p=0.001; \text{Fig. 4})\), but no difference was found between group means on discharge \((F=0.149, df=1, 32, p=0.230; \text{Table 3})\). Eversion AROM improved in both groups from \(10^\circ±6^\circ\) to \(19^\circ±7^\circ\) \((F=59.63, df=1, 32, p=0.001; \text{Fig. 4})\), yet not significantly between group means at discharge \((F<0.001, df=0, 32, p=1.0; \text{Table 3})\).

Independent t-test of post-test mean dorsiflexion AROM by insurance carrier revealed no difference between the 6 subjects covered by workers’ compensation insurance (mean 3.83, SD 7.31), compared to the 15 subjects insured by Blue Cross Blue Shield (mean 2.87, SD 2.87; \(t(19)=0.382, p=0.706; \text{Fig. 5})\). The magnitude of differences in the means (mean difference = 0.97, 95% CI: –4.33 to 6.3) was very small \((\eta=0.008)\).

**STRENGTH:** Repeated measures ANOVAs showed that all subjects improved in dorsiflexion strength \((F=77.99, df=1, 32, p=0.001; \text{Fig. 6})\), yet there was no difference between group means at discharge \((F=0.003, df=0, 32, p=0.954; \text{Table 4})\). Both Evenup™ and control groups reported improved plantar flexion strength \((F=67.18, df=1, 32, p=0.001; \text{Fig. 6})\), with no difference between groups on discharge \((F=0.127, df=1, 32, p=0.724; \text{Table 4})\). Inversion strength for both groups improved \((F=71.05, df=1, 32, p=0.001; \text{Fig. 6})\), with no difference between groups on discharge \((F=0.187, df=1, 32, p=0.668; \text{Table 4})\). As with the other ankle strength measures, eversion for both groups improved \((F=62.90, df=1, 32,\)
p<0.001; Fig. 6), but not significantly between groups at discharge (F=0.002, df=1,32, p=0.961; Table 4).

The Mann-Whitney U-test revealed no difference in strength for: dorsiflexion in the Evenup™ (Md=17, n=17) and control groups (Md=18, n=17): $U=136$, $Z=-5.04$, $p=0.760$, $r=0.09$; plantar flexion in the Evenup™ (Md=16, n=17) and control groups (Md=16, n=17): $U=166$, $Z=0.833$, $p=0.474$, $r=0.14$; inversion in the Evenup™ (Md=18.74, n=17) and control groups (Md=16, n=17): $U=166$, $Z=0.9$, $p=0.474$, $r=0.15$; and eversion of subjects in the Evenup™ (Md=17.3, n=17) and control groups (Md=17.7, n=17): $U=141$, $Z=-0.171$, $p=0.92$ (Table 4).

**Discussion**

The purpose of this study was to compare outcomes of function, pain, ankle strength, and range of motion for those using an Evenup™ to correct walking boot-induced LLI with a similar orthopedic population not using the Evenup™. Patient-reported outcome measures for this study included, LEFS, OSW, and NPRS. Additional outcome measures were AROM and MMS test.
values. Subjects in both control and experimental groups reported statistically significant improvement from beginning to end of the episode of care. Analysis of between-group means at discharge showed clinical relevance regarding pain and function. The entire sample mean LEFS scores pre- to post-intervention improved 30 points, reflecting statistically significant improvement in functional status over time for both groups (p<0.001, Fig. 2A). When comparing group mean LEFS discharge improvements, the Evenup™ group score was 8.4 points better than the control group, which closely approached the 9 points necessary for a minimal clinically important difference (MCID). The MCID of a measure is important in that it enables the clinician to more precisely rate patient outcome changes. Similar to this MCID finding, McDonald et al.18 and Crews et al.4 found subjects improved in function when using the Evenup™, as did Defrin et al.5 when using a full-length shoe insert.

The entire sample mean Oswestry scores pre- to post-intervention improved 10 points (p<0.001; Fig. 3A). When comparing group mean Oswestry discharge improvements, the Evenup™ group score was 4.3 points better than the control group, which approached the 6 points required to achieve the MCID on the Oswestry. Similarly, Golightly et al.13 found 9 of 12 subjects with low back pain and LLI reported improved Oswestry scores with shoe-lift intervention.

The entire sample mean NPRS scores pre- to post-intervention decreased 6 points (p<0.001; Fig. 3A), yet only a minimal difference (0.2) was reported between the groups at discharge (Fig. 3B). The latter result differs from the two Evenup™ studies8,18 and other findings related to shoe/heel-lift intervention for subjects with LLI and low back pain.8,10,11,13 Caution must be taken when comparing the results from these investigations since the self-reported measures were not identical. Also, individual patient responses to leg length discrepancies vary, as people are different, do not respond in the same way, and have different pain thresholds.

Limitations and Future Research Needs

Data collection measures were only taken at pre- and post-intervention, without any follow-up period. Also, there was no real-time data collection during functional activities, as in other investigations.4,18 This study was non-funded, necessitating purely voluntary subject participation. The inherent nature of a walking boot, and the Evenup™, prevented blinding of subjects and investigators. Though a randomized control trial was intended, this did not occur due to subject attrition, which resulted in a small sample size. Lastly, data collection occurred at one location.

The Evenup™ holds potential benefits for all healthcare stakeholders in general, medical and rehabilitation professionals in particular, and especially for the numerous people we serve. Evenup™ use with a walking boot may facilitate a quicker return to ambulation and thereby enhance rehabilitation outcomes for numerous individuals with an array of neurological, musculoskeletal, and orthopedic lower extremity conditions. Additional clinical research is necessary to fully investigate the potential benefits of Evenup™ use when a walking boot is prescribed. Specifically, a multicentered randomized controlled trial is necessary to demonstrate the full potential that the Evenup™ holds for persons prescribed a walking boot.

Conclusion

This experimentally controlled clinical investigation examined Evenup™ use. Although analysis of results from the NPRS, Oswestry, and LEFS self-report measures did not demonstrate statistical significance, a trend of improved function was noted. Statistical differences do

### Table 3. Repeated Measures ANOVA for Ankle AROM (in degrees)

<table>
<thead>
<tr>
<th></th>
<th>Pre</th>
<th>Post</th>
<th>F</th>
<th>df</th>
<th>p</th>
<th>Control</th>
<th>Evenup</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorsiflexion</td>
<td>-9±10</td>
<td>3±5</td>
<td>30.43</td>
<td>1,32</td>
<td>&lt;0.001</td>
<td>1±6</td>
<td>5±5</td>
<td>3±5</td>
</tr>
<tr>
<td>Plantarflexion</td>
<td>48±12</td>
<td>6±11</td>
<td>39.08</td>
<td>1,32</td>
<td>&lt;0.001</td>
<td>6±10</td>
<td>60±11</td>
<td>61±11</td>
</tr>
<tr>
<td>Inversion</td>
<td>15±10</td>
<td>22±7</td>
<td>27±66</td>
<td>1,32</td>
<td>&lt;0.001</td>
<td>21±7</td>
<td>23±7</td>
<td>22±7</td>
</tr>
<tr>
<td>Eversion</td>
<td>10±4</td>
<td>19±4</td>
<td>59±63</td>
<td>1,32</td>
<td>&lt;0.001</td>
<td>19±8</td>
<td>18±4</td>
<td>19±7</td>
</tr>
</tbody>
</table>

### Table 4. Repeated Measures ANOVA for Ankle Strength

<table>
<thead>
<tr>
<th></th>
<th>Pre</th>
<th>Post</th>
<th>F</th>
<th>df</th>
<th>p</th>
<th>Control</th>
<th>Evenup</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorsiflexion</td>
<td>7.3±2.9</td>
<td>11.8±0.61</td>
<td>77.99</td>
<td>1.32</td>
<td>&lt;0.001</td>
<td>11.8±0.53</td>
<td>11.7±0.69</td>
<td>0.003</td>
</tr>
<tr>
<td>Plantarflexion</td>
<td>6.8±2.9</td>
<td>10.8±1.6</td>
<td>67.18</td>
<td>1.32</td>
<td>&lt;0.001</td>
<td>10.6±1.7</td>
<td>11.1±1.5</td>
<td>0.012</td>
</tr>
<tr>
<td>Inversion</td>
<td>6.9±3.1</td>
<td>11.5±0.93</td>
<td>71.05</td>
<td>1.32</td>
<td>&lt;0.001</td>
<td>11.3±1.2</td>
<td>11.7±0.7</td>
<td>0.018</td>
</tr>
<tr>
<td>Eversion</td>
<td>6.8±3.2</td>
<td>11.6±1.0</td>
<td>62.90</td>
<td>1.32</td>
<td>&lt;0.001</td>
<td>11.5±1.2</td>
<td>11.6±0.7</td>
<td>0.002</td>
</tr>
</tbody>
</table>
not always tell the whole story when it comes to patient outcomes and the patient’s perception of improved quality of life and function. LEFS and Oswestry results suggest that Evenup™ use added value in the form of improved patient function.

Key Points

- **Findings**: This is the first study of Evenup™ use by people with lower limb orthopedic conditions either post-traumatic or post-surgery. A trend of improved function was noted in those wearing the Evenup™.

- **Implications**: Clinicians could recommend the Evenup™ device to improve function and minimize pain in individuals using a walking boot.

- **Caution**: Further study of Evenup™ use in a larger sample size is needed.

References