The Effects of Vacuum-Molded Orthotics on Lower Extremity Overuse Injuries

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Orthotics are commonly prescribed for the treatment of lower extremity injuries secondary to hyperpronation. However, the efficacy of vacuum-molded orthotics has not been established. We assessed the effects of vacuum-molded orthotics on pain and level of function in athletes suffering from plantar fasciitis, medial tibia1 stress syndrome, or knee pain secondary to hyperpronation. Fourteen athletes assessed their pain and level of function during athletic activity before being fitted for orthotics (Professional Rx, SuperFeet In-Shoe Systems Inc.) and weekly for 7 weeks following break-in. Five athletes (36%) reported complete pain resolution and eight (57%) reported substantial improvement. Eight athletes (57%) reported full return to athletic participation and five (36%) reported substantial improvement in athletic function. One athlete failed to respond to treatment. Results indicate that vacuum-molded orthotics are an effective treatment for lower extremity overuse injuries secondary to hyperpronation.

Although a number of factors must be considered in the evaluation and diagnosis of lower extremity overuse problems, many of these problems are related to foot structure and abnormal function while weight bearing. Because the foot and ankle complex is the final link in the lower extremity closed kinetic chain, correct arthrokinematic alignment and movement are essential for normal osteokinematic function and consequent attenuation of forces (3, 4, 7). Improper arthrokinematic alignment and movement with subsequent improper distribution and dissipation of forces will lead to joint destruction and disruption of connective tissue and muscle (5, 6).

The ankle and foot are uniquely designed to afford efficient locomotion in a lifetime of repetitive loading on varying terrains at different rates (12). However, abnormal foot mechanics, due to dynamic muscle imbalance and the deterioration of intrinsic stability, may lead to altered muscle and joint function,
and connective tissue changes (4, 19). In addition, improper biomechanics will deter the mechanisms that distribute and dissipate the forces of weight bearing. This, in turn, sets the stage for musculoskeletal overuse, lower extremity pain, and a loss of running abilities (4). If normal biomechanics of the foot and ankle are not present, a myriad of foot, leg, knee, hip, and back problems may result (2, 4, 7, 8, 13, 16).

There are many means of correcting faulty foot/ankle biomechanics and reducing lower extremity pain in running athletes. Proper training and conditioning, including an organized program to enhance flexibility, strength, and proprioception in the lower extremity musculature, can be effective in the management of overuse injuries (16). Restoring proper foot function through mechanical controls via shoe wear, taping, and orthotics is also often effective. Mechanical controls are designed to restore normal alignment of the subtalar and midtarsal joints while controlling excessive pronation and providing timely and effective resupination, which dissipates weight-bearing forces through the kinetic chain (4, 5, 15, 17, 19). Orthotic shoe inserts are most effective in the treatment of symptoms arising from biomechanical abnormalities such as excessive pronation (9). Research has established orthotics as a viable treatment approach for plantar fasciitis, Achilles tendinitis, medial tibial stress syndrome (MTSS), and knee pain, because of the relationship these syndromes have with abnormal foot biomechanics (2, 4, 5, 6, 12).

Providing orthotics to all athletes who could benefit from them is often difficult. Athletes treated in the clinic may not have insurance to cover the expense of the orthotics. Similarly, when high school and college athletes are treated in the training room, the expense must be absorbed by the department budget or by the athlete. Vacuum-molded orthotics may represent a more cost-effective means of providing orthotics to athletes who could benefit from them if the orthotics prove effective in alleviating symptoms of lower extremity overuse injuries associated with hyperpronation. The purpose of this study was to assess the efficacy of vacuum-molded orthotics in providing pain relief and increased function in running athletes with lower extremity overuse injuries.

**Methods**

**Subjects**

Fourteen university student athletes (12 track/cross country, 1 judo, 1 softball) who had lower extremity overuse injuries that had failed to respond to conservative treatment such as ice, muscle strengthening, and stretching and who demonstrated hyperpronation were identified. One subject had more than one lower extremity complaint, which accounted for 15 diagnoses and 14 subjects. Ten males (age = 22.7 ± 4.27 years, height = 181.6 ± 3.0 cm, weight = 77.8 ± 11.3 kg) and four females (age = 19.3 ± 1.5 years, height 167.1 ± 6.6 cm, weight = 58.4 ± 11.0 kg) were prescribed orthotics. The complaints that led to the prescription of the orthotics included MTSS (n = 9), plantar fasciitis (n = 3), and knee pain (patella-femoral pain and patellar tendinitis, n = 3). None had a diagnosis of
fracture in the lower extremity and none had been previously treated with orthotics.

The athletes were evaluated by an experienced physical therapist/athletic trainer (CRD) to determine (a) if their injuries were secondary to lower extremity biomechanical dysfunctions and (b) if their foot structures and lower extremity biomechanics made them candidates for orthotic management. Each athlete received forms explaining the potential risks and benefits of orthotic use and provided informed consent in compliance with university guidelines.

Procedures

Prospective candidates' foot structure and functional mobility were assessed bilaterally. The evaluation involved assessment of first ray mobility, forefoot and rearfoot posture, calcaneal motion, talocrural motion, and navicular drop. The subtalar joint was maintained in neutral during the assessment of foot structure and functional mobility by palpating the talar condyles as described by Magee (11). First ray mobility was assessed by initially pronating the midtarsal joints and then maximally plantar flexing and dorsiflexing the first ray (21, 22). Calcaneal motion was measured by placing the athlete prone with the feet extended over the examination table. The examiner then placed a mark over the midline of the calcaneus at the insertion of the Achilles tendon. A second mark was placed distally on the calcaneus as close to the midline as possible. A line was drawn on the calcaneus connecting the two marks. The examiner then made two marks on the lower third of the leg in the midline. The two marks were joined, bisecting the leg (6, 11). Resting calcaneal position was measured in subtalar joint neutral (STJN) using a standard goniometer (6, 11).

The examiner then fully everted and inverted the calcaneus, and the angular displacement was recorded in each direction from the STJN position (11). With the athlete prone and feet extended over the examination table, forefoot posture was determined by placing one of the arms of the goniometer along the plane of the metatarsal heads with the other arm perpendicular to the bisection line on the calcaneus (11). Dorsiflexion range of motion was assessed in STJN with the knee extended and flexed via standard goniometric procedures. Assessment of navicular drop required that the subject be seated so that the examiner could mark the navicular tuberosities with a writing utensil. The subject was instructed to remain non-weight bearing so that STJN could be obtained while the initial height measurement of the navicular tuberosity was measured in millimeters. The subject was then asked to fully weight bear unilaterally while a second measurement was taken after the foot had fully pronated. The change in navicular height was recorded (2). In addition, leg length differences were evaluated. Subjects with knee pain were also evaluated for tightness in the iliotibial band, hamstrings, and hip rotators. Subjects demonstrating tightness in these muscles were instructed in stretching exercises. A summary of the physical exams is found in Table 1.

Prior to being fitted with the orthotics, subjects evaluated their pain and function using the appropriate graphic rating scales (Figures 1 and 2). The athletes were then fitted for a pair of orthotics (Professional Rx, SuperFeet In-Shoe
### Table 1

**Physical Exam Summary**

<table>
<thead>
<tr>
<th>Exam</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>First ray mobility</td>
<td>64% of the subjects demonstrated hypermobility</td>
</tr>
<tr>
<td>Forefoot posture</td>
<td>3.9° (2.5&quot;) of forefoot varus</td>
</tr>
<tr>
<td>Rearfoot posture</td>
<td>5.1° (2.9&quot;) of rearfoot varus</td>
</tr>
<tr>
<td>Calcaneal inversion</td>
<td>19.7° (3.2&quot;)</td>
</tr>
<tr>
<td>Calcaneal eversion</td>
<td>11.0° (1.8&quot;)</td>
</tr>
<tr>
<td>Navicular drop</td>
<td>16 mm (.36 mm)</td>
</tr>
<tr>
<td>Dorsiflexion in STJN</td>
<td></td>
</tr>
<tr>
<td>With knee extended</td>
<td>-2.3° (4.8&quot;)</td>
</tr>
<tr>
<td>With knee flexed</td>
<td>13° (5.3&quot;)</td>
</tr>
</tbody>
</table>

*Note.* Forefoot posture, rearfoot posture, calcaneal eversion, calcaneal inversion, navicular drop, and dorsiflexion measures represent the means and standard deviations for all subjects.

Systems, Inc., Custer, WA) by a representative from the company. Subjects were instructed on the break-in period prescribed by the manufacturer. Fabrication of these orthotics involves a non-weight-bearing process, during which the midtarsal joints are locked and the subtalar joint is neutral. The orthotic was custom molded to each individual's foot by vacuuming air from a bag sealed around the lower leg. The negative pressure of the vacuum molds the heated orthotic material to the contours of the foot. Fabrication of the orthotics required approximately 15 min. The athlete began to break in the orthotic immediately after fabrication.

Following a 2-week break-in period, the effectiveness of the orthotics was assessed through weekly pain and function measurements (Figures 1 and 2). Athletes completed the pain and function scales for 7 consecutive weeks. In addition, the athletes were asked to note, in a space provided on the function scale, any problems in adapting to their orthotics.

### Data Analysis

Pain and level of function were quantified for statistical analysis. The Graphic Pain Rating Scale represents a continuum of pain on a 16-cm line, which ranges from no pain (0 cm) to worst pain (16 cm) with descriptors spread equally along the line. The pain reported by each athlete was quantified by measuring the distance, in centimeters, from no pain (0 cm) to a mark indicating the athlete's level of pain. Function was divided into three categories: intensity, duration, and frequency. Each category has a scale representing a continuum of function on an 11-cm line that ranges from 0% (0 cm or no athletic participation) to 100% (11 cm or full function). The function reported in each category was quantified by measuring the distance, in centimeters, from 0% to the percent indicated by the athlete. The three measurements from each functional category were summed...
to calculate an overall function score, which was used in data analysis. Therefore, full athletic function would equal 300% (33 cm).

Multivariate analysis of variance (MANOVA) was conducted to identify significant changes in pain and level of function over an 8-week period. Univariate analysis of variance (ANOVA) was then conducted to identify significant changes in pain and function separately. Also, ANOVA was used to determine significant changes in pain and level of function in the MTSS group. Data from the plantar fasciitis group and nonspecific knee pain group were not statistically analyzed due to the small sample size.

Results

MANOVA revealed significant differences in the pain and level of function scores across the eight weekly measurements (Wilks’s lambda = .00693, $p < .001$). Pain decreased, $F(7, 91) = 5.97, p < .01$ (Figure 3), and the level of function improved, $F(7, 91) = 13.04, p < .01$ (Figure 4), following the prescription of orthotics. Of the 14 athletes treated with orthotics, 5 (35.7%) reported complete resolution of symptoms while 8 (57.1%) reported 100% return to function. An additional 8 athletes (57.1%) reported marked decreases in pain while 5 (35.7%) reported substantial increases in function. In other words, 13 (92.8%) reported significant improvements in their pain and levels of function. There was one subject who reported no pain resolution or improvements in functions.

The complaints that led to the use of the orthotics included MTSS ($n = 9$), plantar fasciitis ($n = 3$), and knee pain ($n = 3$). ANOVA revealed significant
Athletic function has been divided into three categories: intensity, duration, and frequency.

- Intensity is the degree to which you can give maximum effort.
- Duration is the amount of athletic participation measured in time.
- Frequency is the number of practices per week.

Please indicate your ability to function during practice throughout the past 72 hours by placing an X on each line at the appropriate percentage. 100% = full function and 0% = you cannot practice at all. This line is to represent your level of function during practice only.

<table>
<thead>
<tr>
<th>Intensity</th>
<th>100%</th>
<th>80%</th>
<th>60%</th>
<th>40%</th>
<th>20%</th>
<th>0%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration</td>
<td>100%</td>
<td>80%</td>
<td>60%</td>
<td>40%</td>
<td>20%</td>
<td>0%</td>
</tr>
<tr>
<td>Frequency</td>
<td>100%</td>
<td>80%</td>
<td>60%</td>
<td>40%</td>
<td>20%</td>
<td>0%</td>
</tr>
</tbody>
</table>

In the space provided please elaborate on your pain and functional limitations. Please note specific improvements as they relate to your orthotics.

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Figure 2 — Percent Function Rating Scale (reduced to fit page).

Improvements in the MTSS group, $F(7, 91) = 380.87, p < .01$. Although the plantar fasciitis group and knee pain group were not statistically analyzed the distribution of results was similar (Figure 3).

There was a strong association between good treatment results and continued orthotic use. Those who reported benefits said that they would continue wearing orthotics. The most common complaint reported was the inability to fit the orthotic in all types of footwear, especially running spikes (71%).

**Discussion**

The results of this study indicate that vacuum-molded orthotics can be helpful in treating a variety of lower extremity overuse syndromes. Ninety-three percent
Figure 3 — Perceived pain index: subjects' report of perceived pain during training. The Week 1 assessment took place before orthotic prescription; Weeks 2–8 are the assessments following the break-in period.

of the athletes reported partial or total relief of pain and partial or complete recovery of function with orthotic use. Four months postprescription 100% of the athletes stated that they continued to wear the prescribed orthotics.

During walking and running, the foot initially hits the ground in a slightly supinated position. The foot then quickly commences to pronate at the subtalar joint with concurrent unlocking of the midtarsal joint (6, 14, 19). This action is necessary to unlock the foot for surface adaptation and shock absorption during walking and running (18). The navicular tuberosity drops from the STJN position during pronation (1, 6, 14), making navicular drop a useful clinical assessment of pronation. Resupination occurs soon after maximum pronation. During midstance the midtarsal joint is locked, the subtalar joint is in neutral, and the ankle is approximately perpendicular to the leg (6, 7, 14, 16, 17, 19). The foot continues to fully supinate to act as a rigid lever during toe-off (2, 6, 19). When pronation is excessive or prolonged, the normal function of the musculature is altered, which may lead to a lower extremity overuse injury (16, 19). Excessive pronation is a compensation for soft tissue or osseous deformity (5). In most cases, excessive pronation occurs at the subtalar joint to compensate for deformities such as hypermobile first ray, forefoot varus, rearfoot varus, tight Achilles tendon, tibial vara, leg length discrepancy, and femoral torsion (5, 6, 16, 19, 21). If subtalar pronation is excessive or prolonged, a proportional amount of obligatory
Figure 4 — Training index scores: subjects' reported training index. The Week 1 assessment took place before orthotic prescription; Weeks 2–8 are the assessments following the break-in period.

Leg internal rotation occurs, straining the structures of the knee and foot (2, 14). In addition, excessive pronation also prevents the foot from obtaining a stable or rigid supinated position during toe-off (2, 14), therefore making the foot less efficient and the gait less powerful (14).

The use of orthotics to control the extent and duration of pronation during the stance phases of gait effectively reduces pain and increases function in patients with lower extremity overuse injuries (5). Our results are consistent with these reports of the effects of orthotics in the treatment of lower extremity overuse injuries. Gross et al. (10) stated that orthotics are most effective in treating lower extremity overuse syndromes arising from biomechanical abnormalities, such as excessive pronation (1, 4–6, 9, 12–14, 19, 20). It is important that the clinician carefully review the athlete’s training program so that training errors that may have contributed to the injury are eliminated. It has been our experience that overuse injuries due primarily to training errors do not respond to orthotic management.

One athlete, a pole vaulter, failed to respond to treatment with orthotics. Most of this athlete’s sport-specific training was done while wearing spikes. The orthotics that were molded for him did not fit properly in the spikes. Thus, we attribute this poor result to the inability to provide motion control during a large part of the athlete’s training regimen.
In our experience, orthotics molded from plaster or foam molds are effective in managing overuse injuries secondary to hyperpronation. The efficacy of vacuum-molded orthotics has not been previously reported. Vacuum-molded orthotics offer the advantage of immediate delivery. The athlete can begin breaking in the orthotics on the same day as the evaluation. In addition, because the fabricating apparatus can be brought on-site, vacuum-molded orthotics may be a more cost-effective means of providing orthotics to high school and college athletes treated in the training room. Our results indicate that vacuum-molded orthotics are effective in the management of lower extremity overuse injuries secondary to hyperpronation.

References

