Research Article

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Pedobarograph based prefabricated orthotics reduces self-reported minor injuries and improves comfort whilst running

Abstract

Running is becoming an increasingly popular sport which has led to an increase in running-related injuries (RRIs). The study is a pilot evaluation whether pedobarograph based prefabricated orthotics decreased self-reported minor injuries, increased comfort and increased performance.

Data was collected from 37 voluntary runners aged between 20 and 75 with previous running experience and no ongoing issues of foot pain. Based on the recommendations of the pedobarograph, one of the 4 Sport Orthotics (L 400 series - orthotic (Lynco® Aetrex[1]) as recommended by the pedobarograph was provided. After acclimatisation for 2 weeks, participants ran with and without the orthotic on alternate weeks and recorded distance, time, comfort and the presence of any injuries or pain.

Sixty-one runners were recruited for the study through social media promotion (Facebook). 5 runners voluntarily withdrew from the study. 37 participants (21 females and 16 males) provided data on 358 runs (214 runs with the Orthotic and 144 runs without the Orthotic.

The mean rate of self-reported minor injuries was 28.21% (101/358 runs). With the Orthotic the injury rate was 21.03% (45 of the 214 runs) and without the Orthotic the injury rate was 38.89% (56 of the 144 runs) (38.89%) showing a 17.8% reduction of self-reported minor injuries.

The average comfort score measured on a Likert scale of -5 to +5 when running with the orthotic was 2.45 (sd=2.45), as compared to when running without the orthotic 0.44 (sd=1.99) showing a 18.27% improvement of comfort with the Orthotic.The performance /average velocity of the participants when running with the orthotic was 10.52km/hr (sd=2.25) as compared to when running without the orthotic at 10.1km/hr (sd=2.53). This did not reach statistical significance.

Keywords: running, self-reported, minor injuries, orthotics, comfort, injuries, performance, average velocity

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George Ampat,[1] Robert Baxter,[2] Fionnuala Geoghegan[3]

[1]Clinical Teacher, School of Medicine, University of Liverpool, England
[2]Medical Student, School of Medicine, University of Liverpool, England
[3]Sports & Spinal Injury Clinic, University of Bolton Bolton, England

Correspondence: George Ampat, Clinical Teacher, School of Medicine, University of Liverpool, Cedar House, Ashton Street, Liverpool, L69 3GE, England, Email georg@feetandspine.com

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Introduction

Running is the most accessible sport in the world. There are no entry barriers, nor specialized equipment required to take part. The story of Parkrun shows how popular running has become in the last two decades. Parkrun started in 2004 in Bushy Park Teddington, UK with 13 runners.[2] From its humble beginnings in Bushy Park Teddington, these events now occur in 23 countries across 5 continents.[2] In UK alone Parkrun occurs in more than 609 locations with more than 26 million runs recorded.[3] Data submitted to the UK House of Commons state that running has become the most popular sport in 2016 / 17 among 16+ adults. 15% participated in running as compared to 5% in football.[4]

Unfortunately with increased popularity comes the increased risk of injuries. The incidence of running-related injuries can be as high as 92.4%.[5]

Identifying modifiable risk factors to reduce running related injuries has not been easy. Many randomized control trials have failed to provide answers.[6] Orthotics have shown some benefit in reducing running related injuries. A Cochrane review suggested that custom-made biomechanical insoles may be more effective than no insoles for reducing shin splints.[7] There is also evidence that custom moulded foot orthotics may improve comfort and running economy.[8]

There are two broad types of orthotics. Custom made and prefabricated.[9] Manufacturing custom made foot orthotics are labor intensive. A negative cast impression of the patient's foot is prepared in a foam box. A positive plaster cast is then prepared from the foam box. Soft or hard material is then heated and vacuum pressed over the plaster cast. The moulded material is then trimmed and ground down to the finished product.Customized foot orthoses are generally considered the gold standard.[10]

Prefabricated are mass produced to fit a generic foot shape. Prefabricated orthotics can be either an off the shelf orthotic or provided following pedobarography. Aetrex® manufactures a range of prefabricated orthotics for various indications.The range includes 46 varieties for male and 42 varieties for females.[1] The orthotic is provided following a static pedobarograph – I Step®. For purposes of this study we only included 4 male and 4 female varieties. They were the standard sports series.

Much of the evidence of the benefits of running with Orthotic has been from custom made orthotics. There is no published research to date to compare the benefits of a prefabricated orthotic provided following a pedobarograph for reducing running related injuries.

In addition Redmond et al.[10] suggests that there is no comparable differences in plantar pressures between custom made orthotics and prefabricated orthotics. Furthermore custom orthotics are at least 2.5 times more costlier than prefabricated Orthotics.

We aimed to carry out a pilot study exploring the benefits of wearing a prefabricated orthotic provided following a pedobarograph in order to determine whether any significant positive difference could be recorded.[11] A protocol for the research study was submitted to the Sports Science Department at the University of Bolton for ethical approval. The departmental committee sanctioned conduct of the study.

Materials and methods

We recruited volunteers through Social media posts (Facebook). The volunteer's basic information was obtained via a Survey Monkey link which clearly enumerated the inclusion and exclusion criteria. All adults aged between 20 and 75 who have had reasonable participation in running over the past two years were included. Our criteria for reasonable participation was anyone who had run 365 miles in each of the preceding 2 years i.e an average of a mile per day over the last 2 years. The exclusion criteria were any ongoing serious illnesses, orthotic use at present or in the past, current pain in the lower limbs or any injury, any foot surgery in their lifetime and any non-foot surgery over the last 6 months prior to enrolment. We excluded participants who had used an orthotic previously to avoid any pre-existing bias for or against an orthotic.

The participants underwent a mini interview and examination with an Orthopaedic Surgeon (the senior author). Written consent for participation was obtained. A static pedobarograph (IStep) was undertaken and the Orthotic suggested by the I Step was provided to the participant. The I Step scanner measures the static force exerted by the foot whilst standing. The scanner has about 3744 force sensing resistors. After standing for 10 seconds, the scanner provides a pressure map and suggests an Orthotic based on a preprogrammed algorithm (Figure 1 & 2). The I Step scanner was programmed to only suggest the Sports Orthotics. There are 4 variants of the Sports Orthotic, which are the 400, the 405, the 420 and the 425. The 400 has an arch support with a cupped heel. The 405 has an arch support, a cupped heel and a metatarsal pad. The 420 has an arch support and an additional medial post. The 425 has an arch support, a medial post and a metatarsal pad. For a neutral foot the IStep scanner would suggest a 400 Orthotic. For a low arch or flat foot the scanner would suggest a 420 Orthotic which has a medial post. If there was increased force transmitted through the ball of the foot, the scanner would suggest an Orthotic with a metatarsal pad. The 405 and the 425 had an inbuilt metatarsal pad. For a neutral foot with increased force transmission through the forefoot the scanner would suggest a 405 Orthotic and for a low arch or flat foot with increased force transmission through the forefoot the scanner would suggest a 425 Orthotic. If there was also significant reduction of the force through the forefoot the scanner would suggest an Orthotic with a metatarsal pad. Table 1 provides the algorithm.

Based on the shoe size of the participant, the Orthotic recommended by the pedobarograph was trialled with the participant. Once the orthotic was comfortable in the running shoe the participant was finally enrolled into the study.

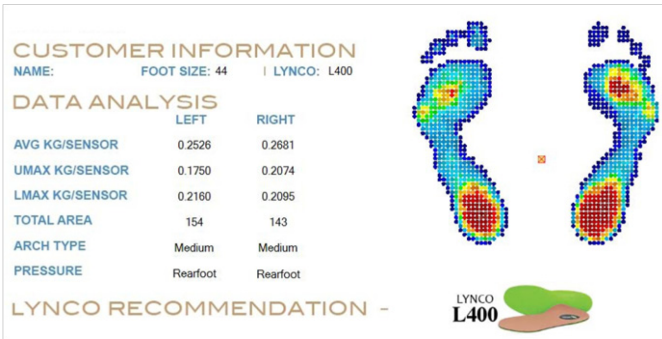

Figure 1 Shows the pedobarograph of a Male participant with medium arches and the pedobarograph recommended a L400 Orthotic.

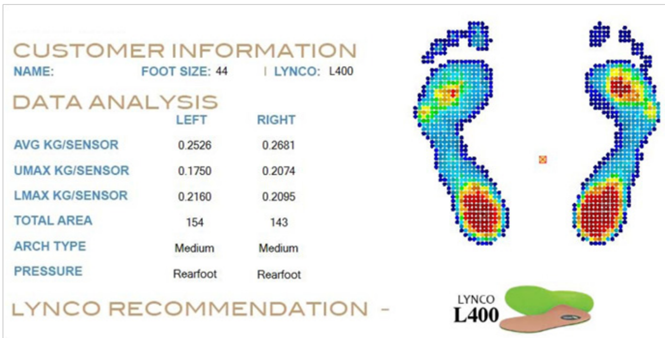

Figure 2 Shows the pedobarograph of a Male participant with high arches and increased force transmission through the forefoot. The pedobarograph recommended a L405 Orthotic with a Metatarsal pad.

Table 1 Shows the 4 variations available with the Orthotic. 2 Hind foot options (Cupped and posted) and 2 Forefoot options (Neutral and supported with metatarsal pad)

IStep - algorithm	Orthotic	Rear foot	Forefoot
Normal foot	400	Cupped R	Neutral F
Increased force transmission through the forefoot	405	Cupped R	Supported F
Low arch	420	Posted R	Neutral F
Low arch with increased force transmission through the forefoot	425	Posted R	Supported F

All participants were sent an email explaining the study protocol and how the results would be recorded. The participants were given two weeks running their normal routine to acclimatize to their orthotic and report any problems, no data was collected in these two weeks. Participants could withdraw at any point if they no longer wanted to continue. It was after this two-week acclimatisation period the true study period began. The true study period was over the following four weeks. During these 4 weeks the participants were asked to carry out their normal running routine, including their usual running routes and to avoid group running if possible so their running pace would not be influenced by the runners around them. The participants were asked to use the Orthotic on an alternate week basis. Therefore during week 1 and week 3 of the study they were requested to use the orthotic in their normal running shoe and during week 2 and 4 of the study they were requested not to use the orthotic and just use their normal running shoes. They were asked to record the data after every run either via a survey monkey link or into a spreadsheet or manually on paper.The spreadsheet/scanned paper copy could be emailed to the researchers at the end of the four week trial period.

The participants were asked to log data from a minimum of 10 runs during the study period. The participants were advised that any unusual pain during or after the run was to be documented as a minor running related injury (RRIs). They were also advised to record any unusual pain over the four weeks of the study. Comfort was recorded using a linear Likert scale from '-5' to '+5' with the bottom of the scale (-5) representing the most severe discomfort when running and the top of the scale (+5) representing the maximum comfort. The data recorded also included the distance and time of their runs. From the distance and time the average velocity / performance could be calculated. Runners were encouraged to use online applications such as Stravaand MapMyRun to record the distance and time.

Results

61 runners were recruited into the study and provided with Orthotics. Five participants had to withdraw from the trial due to pain and injuries. Two attributed this directly to the orthotic, two other were unrelated injuries and one participant became pregnant following enrolment into the study. No data from these participants were included into the study. A further 19 participants who were enrolled into the study and were provided with the Orthotic failed to record any data in spite of repeated reminders. The remaining 37 runners (21 female and 16 male) recorded data on 358 runs with a total distance of 2852kms. Their age range at the start of the study was 23 to 60. Of the 37 runners enrolled, 29 participants used the neutral 400 Orthotic, 5 used the 405 orthotic with metatarsal pad, 1 used the 420 orthotic with the medial post and 2 used the 425 orthotic with the medial post and the metatarsal pad. The study ran over an 8 month period from October 2017 to May 2018.

Of the 358 runs, 214 were with the Orthotic and 144 were without the Orthotic. Any pain or discomfort was considered as a minor running related injury (RRI). The mean rate of injuries was 28.21% (101/ 358 runs). With the Orthotic the rate was 21.03% (45 of the 214 runs) and without the Orthotic it was 38.89% (56 of the 144 runs) (38.89%).Our study showed a 17.8% reduction of self-reported minor injuries with the use of the Orthotic. Relative risk of 0.54.

The most usual body part in which pain was reported was the feet 34.6% followed by the Knee at 20.79%. The various body parts in which pain was reported can be found in Table 2.

Table 2 Shows the number of minor injuries recorded in the different regions

Body part	Numbers	Percentage
Feet	35	34.65%
Knee	21	20.79%
Shin	14	13.86%
Heel	11	10.89%
Ankle	4	3.96%
Calf	4	3.96%
Foot	3	2.97%
Hip	3	2.97%
Hamstrings	2	1.98%
Quads	2	1.98%
Lower leg	1	0.99%
Not known	1	0.99%
Total	101	100.00%

Table Continues...

The comfort score was measured on a Likert scale of -5 to +5. The mean comfort score whilst using the orthotic was 2.45. The mean comfort score without the orthotic was 0.44. The comfort increased by 2.01 on a -5 to + 5 scale by using the orthotic. This achieved statistical significance by the independent student t test (P< 0.01).

The average velocity/performance of the participants with the orthotic was 10.5kms/hr and without the orthotic was 10.1km/hr. Therefore the runs recorded with the orthotic worn were completed at a higher average velocity. However this did not achieve statistical significance.T-test (356) = -1.577; p-value=0.12.A summary of the results is provided in Table 3.

Table 3 Shows overall results. There is a relative risk reduction of minor injuries of 0.54 with the Orthotic and the comfort increased by 2.01 points with the Orthotic

	Mean overall	Mean with orthotic (SD)	Mean without orthotic (SD)	Comments
Rate of injury	0.28	0.21	0.39	Relative risk reduction of injuries with Orthotic 0.54
Mean of comfort (-5 to +5)	1.63	0.44 (1.99)	2.45 (2.45)	Comfort increased with Orthotic 2.01 points (P< 0.01)
Mean of speed (Km per Hour)	10.34 km/h	10.11km/h (2.53)	10.52km/h (2.25)	Speed increased with Orthotic0.41km/h (p 0.12)

Discussion

The range of injuries sustained whilst running is varied. A systematic review identified 28 different running related injuries.[12] Medial tibial stress syndrome was the commonest (incidence ranging from 13.6% to 20.0%) followed by Achilles tendinopathy (incidence ranging from 9.1% to 10.9%) and plantar fasciitis (incidence ranging from 4.5% to 10.0%).[12]

There are however some disparities in the definition of a running related injury and based on this disparity there is also a disparity of the incidence of running related injury.Bovens etal.[13] define any physical complaint developed in relation with running activities and causing restriction in running distance, speed, duration or frequency as an injury.[13] Based on this broad definition it is likely that the rates of injuries are higher. However a recent consensus group has defined a running related injury as a musculoskeletal pain in the lower limbs that causes a restriction or stoppage of running (distance, speed, duration, or training) for at least 7 days or 3 consecutive scheduled training sessions, or that which requires the runner to consult a physician or other health professional.[14]

Taunton et al.[15] have classified the spectrum of severity into 4 grades. Grade 1 - pain only after exercise; Grade 2 - pain during exercise, but not restricting distance or speed; Grade 3 - pain during exercise and restricting distance and speed; Grade 4 - pain preventing all running.

In our study we used the wider definition of any pain that occurred with running or Taunton Grades 1 to 3. This was to enable us to identify all discomfort that ensued with running.Our study showed that the rate of running related injuries decreased by 17.8% with the use of an Orthotic. Relative risk 0.54.

A Cochrane review[16] found orthotics could play a key role in avoiding stress fractures.Malisouxet al.[17] showed that motion control shoes where the midsole hardness is 15% higher than the lateral part reduced running related injuries. In their study 32.4% of participants in the standard shoe group recorded injuries whilst only 17.6% of the participants in the motion control shoe group recorded injuries. Relative risk 0.54.Though the reduction of the relative risk in our study is comparable to the study by Malisouxet al.[17] it should be noted that our study was a pilot study with 358 runs recorded as compared to 12,558 runs recorded by the Malisoux study.

Comfort with footwear is dependent on mechanical, neurophysiological and psychological factors.[18] The fit, aesthetics, cushioning, foot sensitivity and mobility all contribute towards comfort.[19] The assessment of comfort can be performed on various rating and ranking scales, including the Visual Analogue Scale (VAS), the Likert Scale (LS), Yes-No questions (y/n) and ranking by simple sequencing.[20]

We recorded comfort on an 11 point Likert scale with -5 representing maximum discomfort and +5 representing maximum comfort. We only recorded an overall comfort score. In addition to overall comfort, eight specific comfort scores can also be documented. These specific comfort scores are on forefoot cushioning, heel cushioning, medio-lateral control, arch height, heel cup fit, shoe heel width, shoe forefoot width, and shoe length.[19]

In our study the orthotic provided an improvement in comfort by 18.27%.This is comparable with previous recorded improvement of comfort score of 14%. They however computed an overall score from a sum score of 5 specific comfort measures.[21]

It also seems that there is a positive relationship between comfort and reduction of injuries. Mundermann[22] in his study of 106 soldiers used 6 different insoles. 5 of the insoles were selected by the participants as the most preferred and comfortable insole with about the same frequency. Irrespective of the type of the insole the test group had 53% fewer lower extremity injuries than the control group. Thus it seems that comfort of insoles is an important factor for injuries.

Foot pressure-measuring equipment can be used to test the effectiveness of orthoses.[23] However controversy exists regarding the benefits of pedobarography. Choi et al.[24] identified that pedobarography showed low diagnostic correlation.Though we provided the Orthotic based on a pedobarograph we did not collect data to compare between using and not using a pedobarograph.

Performance in running events is the time required to cover the event distance, which is also expressed as the average velocity.[25] Running performance is multifactorial, and clearly varies by distance. Sprinting requires high levels of anaerobic functioning and leg power whilst distance running performance is dependent on high running economy and avoiding non-productive movements. Our study showed a slight improvedaverage velocity / performance when using the Orthotic but the difference was not statistically different.

Limitations

The main drawback of our study was the small numbers. However this was a pilot study and that may justify the small numbers. The other drawback of the study was in the study design. Participants ran with and without the orthotic on alternate weeks. It is possible that the participants developed an injury in the previous week but reported the same only in the following week. There was no wash out period between running with and without the orthotic.However as stated earlier, the definition of a running related injury is varied. We had a pilot study with amateur runners and small numbers. We wanted to identify the lower grades of injuries as defined by Taunton Grades 1 to 3. These are described as pain that occurs with exercise. By definition the pain has to present during the workout. We identified these injuries and hence a washout period was not required. It would also be difficult to have a washout period for runners if they are in the habit of running regularly.

Conclusion

Our data suggests that pedobarograph suggested prefabricated orthotics reduce self-reported minor running related injuries and provide better comfort but with no significant improvement of average velocity / performance. Based on these findings we are proposing to conduct a larger study.

Acknowledgments

None.

Declaration of interest

George Ampat has a commercial relationship with Feet and Spine (www.feetandspine.com) which is an Aetrex Dealer in the UK.Robert Baxter and FionnualaGeoghegan have no conflict of interest.

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