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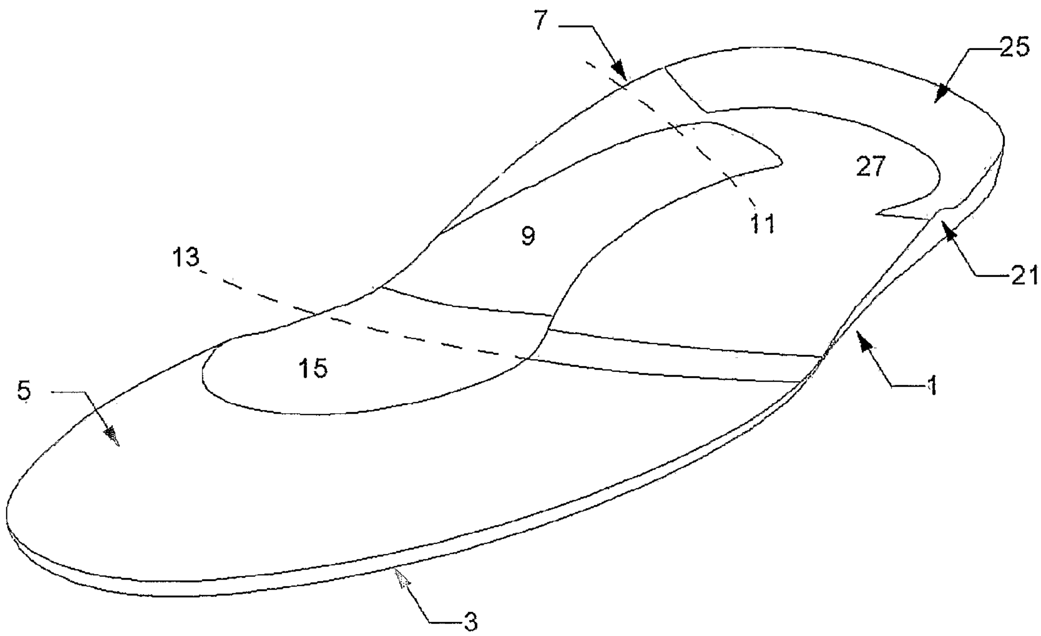
(54) **Title:** A SHOE ORTHOTIC



(57) **Abstract:** A shoe orthotic or an inner sole of a shoe for supporting a foot comprising a dorsal surface (5), a plantar surface (3) and an arch support (7) wherein there is provided in the dorsal surface of the orthotic a groove (9) which is disposed laterally from the medial arch support of the orthotic such that the groove modulates the ability of the first ray of the foot to plantar flex.

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A SHOE ORTHOTIC

FIELD OF THE INVENTION

The present invention relates generally to foot orthotics to use in conjunction with various types of footwear. More particularly, the present invention relates to pre-form orthotics which improve the stability of the foot.

BACKGROUND TO THE INVENTION

A functional foot orthotic is a shoe insert that provides support for the arch of the foot and also controls pronation of the foot. Custom made orthotics are individually tailored for the needs of the patient which requires considerable expertise on the part of the podiatrist assessing the problems with the feet and on the part of the orthotics designer. Often the process of obtaining a suitable shoe orthotic of this type can take weeks, if not months, and numerous visits to the podiatrist, while the particular needs of the patient are ascertained. By comparison, pre-form orthotics are orthotics that are manufactured on a large-scale basis and provide support to the arch of the foot and control pronation of the foot. However, such orthotics are not tailored to the individual needs of the patient and, as a consequence, do not necessarily meet their needs.

There is a need for orthotics that can be simply and cheaply manufactured yet provide a greater level of support and stability to the foot than the pre-form orthotics known in the art.

SUMMARY OF THE INVENTION

The present inventors have found that a pre-form orthotic that contains a feature, or collection of features, that facilitates the windlass mechanism, results in greater foot stability than prior art orthotics. Further, the present inventors have found that the incorporation of such features in a pre-form orthotic provides a general improvement to the stability of the foot. Surprisingly, the incorporation of these features provides a general improvement to foot stability and comfort without compromising the support provided by the orthotic. This is surprising because it was previously thought that features of this nature should only be introduced if there was an indication of arch irritation or the like in the patient. While not being bound by theory, it is believed by the present inventors that the features provide the associated benefits by facilitating the windlass mechanism.

The windlass mechanism comes into effect as the foot enters the transition from heel lift into propulsion. At this stage in the gait cycle, the ligamentous structures in the arch of the foot tighten as the body weight moves forward, allowing the joints of the foot to brace against each other and produce a more rigid, stable structure for effective forward propulsion.

Accordingly, in a first aspect, the present invention provides a shoe orthotic, preferably a pre-form orthotic, for supporting a foot comprising a dorsal surface and a plantar surface and an arch support wherein there is provided in the dorsal surface of the orthotic a groove which is disposed laterally from the medial arch support of the orthotic such that the groove modulates the ability of the 1st ray of the foot to plantar flex.

The present inventors have found that effective plantar flexion of the 1st ray of the foot promotes the windlass effect.

In a second aspect of the present invention there is provided an insole of a shoe comprising a dorsal surface and an arch support wherein there is provided in the dorsal surface of the insole a groove which is disposed laterally from the medial arch support of the insole such that the groove modulates the ability of the 1st ray of the foot to plantar flex.

Throughout this specification, the word "comprise", or variations such as "comprises" or "comprising" will be understood to imply the inclusion of a stated element, integer or step, or groups of elements, integers or steps, but not the exclusion of any other element, integer or step, or groups of elements, integers or steps.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not taken to be an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed in Australia before the priority date of each claim in the application.

The nature of the present may be more clearly understood by reference to the following non-limiting description.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is a perspective view of a full length left foot orthotic of an embodiment of the present invention.

Figure 2 is a side view from the lateral direction of the full length left foot orthotic of Figure 1.

Figure 3 is a top view of the the full length left foot orthotic of Figure 1.

Figure 4 is a perspective view of a three-quarter length left foot orthotic of a further embodiment of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The present invention provides a shoe orthotic, preferably a pre-form orthotic, for supporting a foot comprising a dorsal surface and a plantar surface and an arch support wherein there is provided in the dorsal surface of the orthotic a groove which is disposed laterally from the medial arch support of the orthotic such that the groove modulates the ability of the 1st ray of the foot to plantar flex.

Preferably, the groove extends from a point slightly proximal to the mid line of the arch support and extends distally along the dorsal surface of the orthotic to the metatarsal breakline.

Preferably, the depth of the groove relative to the dorsal surface is greatest in a portion distal to the mid line of the arch support and the width of the groove tapers outward from the proximal end of the groove to the distal end of the groove.

In a preferred form, there is provided in the dorsal surface an indentation positioned at the head of the 1st metatarsal and continuing under the proximal portion of the proximal phalange such that the indentation modulates the ability of the 1st ray to plantar flex.

Preferably, the indentation is located at the distal end of the groove and is continuous with the groove.

Preferably, the indentation is a bowl-shaped indentation. More preferably, the bowl-shaped indentation has a diameter which is approximately one third of the width of the orthotic at the distal end of the groove.

The indentation provides additional freedom for the 1st ray to plantar flex and, as a consequence, further serves to promote the windlass effect.

In a further preferred form, wherein the orthotic is a three-quarter length orthotic, the distal border of which terminates at the metatarsal break point, a portion of the orthotic at the head of the first metatarsal is cut away such that the cut away portion modulates the ability of the first ray to plantar flex.

In another preferred form, there is provided an increase in the declination of the medial dorsal surface distal to the midline of the arch relative to the declination of the lateral dorsal surface distal to the midline of the arch such that the increase in the declination of the medial dorsal surface modulates the ability of the 1st ray to plantar flex.

Preferably the increase in the declination of the medial dorsal surface is present in a region extending from the midpoint of the arch through to the metatarsal breakline.

In a yet further preferred form, the present invention provides an elevation of the orthotic surface at a point under the cuboid of the foot on the lateral edge of the orthotic such that the elevation modulates the ability of the 1st ray to plantar flex.

The cuboid of the foot is located proximal to the base of the 5th metatarsal of the foot.

It would be understood by a person skilled in the art that the features of each preferred form of the orthotic could readily be combined with the features of another of the preferred forms.

The orthotic can be made from any suitable material, preferably the orthotic is made from polyurethane material which displays superior shock absorption and durability when compared to other materials known in the prior art.

Turning to Figure 1, the present invention provides in a preferred embodiment a full length pre-form shoe orthotic **1** for supporting a foot (not shown) having a plantar surface **3** and a dorsal surface **5** and an arch support **7**.

For the purposes of discussion, the orthotic of this preferred embodiment has an average thickness from about 3 to 6 mm, a length of about 255 mm and a width at its greatest point of about 90 mm. It would be well understood by those skilled in the art that references to distances in the discussion below are relative to the dimensions of this preferred embodiment and would be different for orthotics of different dimensions.

A plantar fascial groove **9** is disposed laterally from the medial arch support **7** of the orthotic **1**. The groove **9** extends from a point slightly proximal to the mid-line **11** of the arch support **7** to the metatarsal breakline **13**. The function of the groove **9** is allow the 1st ray (not shown) to effectively plantar flex to facilitate the windlass mechanism.

The depth of the plantar fascial groove **9** , as measured relative to the dorsal surface **5**, is at a maximum in a portion of the groove **9** distal to the centre line of the arch **11** but proximal to the metatarsal break line **13**. The maximum depth relative to the dorsal surface **5** is approximately 2 to 3 mm. In width the groove ranges from about 8mm at the start of the groove and gradually tapers out to be about 30 mm at the end of the groove at the metatarsal break line **13**.

A 1st metatarsal indentation **15** is located at the head of the 1st metatarsal (not shown) of the foot and continuing under the proximal phalange (not shown). In this preferred embodiment the 1st metatarsal indentation is in a bowl shape and is present as a continuation of the plantar facial groove **9**. The indentation **15** is between about 2 to 4 mm in depth, leaving about 1 to 2mm of thickness. This arrangement of the orthotic **1** allows for the 1st ray to effectively plantar flex while still providing cushioning and support under the 1st metatarsal.

A cuboid notch **21** which is an elevation of the dorsal surface at a point under the cuboid (not shown) of the foot at a point proximal to the base of the 5th metatarsal (not shown) further assists in allowing the 1st ray to plantar flex by elevating the remainder of the foot relative to the 1st ray. In this embodiment the elevation of the cuboid notch **17** is in the order of 2 to 3 mm relative to the dorsal surface **5**. The elevation extends approximately 2 cm laterally to medially and tapers to the level of the dorsal surface **5**.

There is an increase in the declination of the medial dorsal surface **5** of the orthotic **1** distal to the midline **11** of the arch support **7** relative to the declination of the lateral dorsal surface **5** distal to the midline of the arch support **7**. That is, in viewing the declination of the dorsal surface **5** of the orthotic **1** moving from the midline **11** of the arch support **7** distally and anteriorly along the dorsal surface **5** of the orthotic **1**, the medial portion of the orthotic **1** is reduced in height for the 1st metatarsal (not shown) from what it would otherwise normally be in relation the 2nd metatarsal to 5th metatarsals (not shown). The region of reduced height further allows the first ray to plantar flex. The increase in declination is most clearly illustrated in Figure 2 in which the declination of the arch support **7** under the 1st metatarsal is indicated by a dotted line **17** for an orthotic that does not include the increased declination of the medial dorsal surface **5** and by a single black line **19** for the orthotic according to this preferred embodiment.

The function of this increased declination of the medial dorsal surface **5** is to improve plantar flexion of the 1st ray and as a consequence facilitate the windlass effect.

Also illustrated in Figure 2 is a plurality of nodules **23** which continue on the plantar surface **3** of the orthotic **1** and act to increase the surface area of the orthotic **1** over which weight is distributed. In a further preferred form (not shown) the nodules are removed from beneath the 1st metatarsal indentation **15**. This allows the 1st ray to further plantar flex and enhances the windlass mechanism.

An elevation from the lateral to the medial at the very rear of the orthotic in a triangular wedge shape **25** function to invert the calcaneous or rear foot without the need for excessive medial arch height. A low heel cup **27** functions to ensure that excessive pronation is not provided by the orthotic.

It will be understood that additional features common in the art may also be incorporated in the orthotic. For instance, the orthotic may include a cover material (not shown).

Turning to Figure 4, an embodiment of the present invention in which the orthotic is a three-quarter length orthotic is shown. The three-quarter length orthotic shares many of the features of the full length orthotic although the 1st metatarsal indentation **15** is not present. Instead, a portion **29** of the orthotic which in the full length orthotic would correspond to the 1st metatarsal indentation **15** may be removed in order to provide a similar effect to the 1st metatarsal indentation **15** in the full length orthotic. This portion **29**, the removal of which is termed a 1st metatarsal cut out, is represented by line **31** in Figure 4.

EXAMPLE

A study was undertaken in order to compare orthotics according to the present invention with prior art orthotics. The study investigated the force needed to establish the windlass mechanism during static stance in 25 subjects while barefoot and while standing on two different foot orthoses. One of the orthoses, in accordance with the present invention, included a plantar fascial groove. The other orthoses was used for the purposes of comparison and did not include a plantar fascial groove. The force required to establish the windlass mechanism was significantly lower ($p<0.001$) with the foot orthoses with the plantar fascial groove.

Introduction

Foot orthoses are widely used to treat biomechanical dysfunction of the lower extremity. Several theoretical frameworks underpin how foot orthoses alter lower limb kinematics and kinetics with there being no consensus of understanding of the reasons for there clinical effectiveness (1,2,3). Foot orthoses may achieve their clinical effect by support the medial longitudinal arch, they may invert the rearfoot and affect skeletal alignment, they may work by altering sensory input or by facilitating the windlass mechanism. The windlass mechanism, originally described by Hicks (4) is one mechanism by which the foot can raise the arch, supinate the rearfoot and become a more stable structure. As the hallux dorsiflexes during gait, the plantar fascia is pulled around the first metatarsal head (the windlass) causing the metatarsal to plantarflex and the medial longitudinal arch to be raised. If it was possible to use foot orthoses to lower the force that is needed to establish the windlass mechanism, it is assumed that this is desirable as it should facilitate the foot being able to support itself. The aim of this study was to compare the force during static stance to establish the windlass mechanism of identically shaped foot orthoses with and without a plantar fascial groove.

Method

Healthy asymptomatic subjects who were free of foot pathology that would interfere with normal first metatarsophalangeal joint dysfunction were recruited for the study.

An apparatus was constructed which consisted of a platform for subjects to stand on in their normal angle and base of gait. The platform was hinged in the area of the first metatarsophalangeal joint so it could be elevated to any desired angle. A screw mechanism could fix the angle and the force plantarflexing the hallux was measured in Newtons with a Memesion force gauge. The force that was plantar flexing the hallux was considered to be the force that was needed to establish the windlass mechanism. Previous testing showed the device was reliable (5).

Two prefabricated foot orthoses were used. One of the orthoses, in accordance with the present invention, included a plantar fascial groove. The other orthoses was used for the purposes of comparison and did not include a plantar fascial groove. In all other respects they were identical. They were constructed of 3mm thick polypropylene.

The procedure for testing involved subjects standing on the platform in their angle and base of gait, with the long axis of the foot to be tested placed parallel with the platform.

The centre of the medial side of the first metatarsophalangeal joint was identified by dorsiflexing the joint several times. The foot was then moved so that it was centred directly over the hinge of the platform. The hinged of the platform was attached to a dial with marks place at different degrees. The hinged platform was elevated to measure the force at 8, 18, and 25 degrees of dorsiflexion. The procedure was carried out three times at each angle with the subject barefoot and standing on both the two different foot orthoses. The mean of each of the three tests at each angle was used for the analysis.

Results

The study was performed on the left foot of 25 subjects (mean age: 24.8 years; mean weight: 68.8 kgs; 5 male; 10 female). The mean force (Newtons) under the hallux at each degree of dorsiflexion is reported in table one.

	Barefoot	Orthoses – no groove	Orthoses - groove	*p*
8 degrees	8.8 (±2.7)	6.7 (±2.9)	4.8 (±1.9)	<0.001
18 degrees	18.4 (±5.4)	14.0 (±6.2)	8.4 (±5.3)	<0.001
28 degrees	48.1 (±8.4)	39.0 (±6.9)	31.5 (±8.3)	<0.001

Table One: Force under the hallux (Newtons) at each of the 3 angles of hallux dorsiflexion and 3 different conditions.

Using Friedman's test for a one sample repeated measures design, the results were all significantly different ($p<0.001$). Post hoc analysis using a paired t-test shows that the different was significant between all three conditions.

Discussion

This study has shown that in healthy subjects a standard foot orthoses with a groove to accommodate the plantar fascia is effective at lowering the force to establish the windlass mechanism compared to an identically shaped foot orthoses without a groove. The windlass mechanism is one means by which the foot is able to support itself. The tension that is established in the plantar fascia during hallux dorsiflexion as the heel comes off the ground, raising the medial longitudinal arch and inverting the rearfoot. It could be assumed that if the force that is needed to establish the windlass mechanism is lowered, then this should facilitate gait and stability of the foot. The reduction seen in this study in the force needed to establish the windlass mechanism with a plantar fascial groove could be considered desirable for gait efficiency.

This study needs to be interpreted in the context of the assumption that the force to dorsiflex the hallux during gait is a proxy for a measure of the force needed to establish the windlass mechanism. The measurement of this force has been done in static stance with the dorsiflexion of the hallux assumed to approximate what happens during dynamic function. Despite these limitations this study has shown that a groove to accommodate the plantar fascia facilitates the windlass mechanism and therefore may be effective in improving gait efficiency.

The results of this study go some way to confirming the belief of the present inventors that the benefits observed for orthotics of the present invention (ie a general improvement to foot stability and comfort without compromising the support provided by the orthotic) are a consequence of the facilitation of the windlass mechanism.

It will be appreciated by persons skilled in the art that numerous various and/or modifications may be made to the invention as soon in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are therefore to be considered in all respects as illustrative and not restrictive.

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5. Payne CB: Measuring the force to establish the windlass mechanism in the foot (in press)

CLAIMS

1. A shoe orthotic for supporting a foot comprising a dorsal surface and a plantar surface and an arch support wherein there is provided in the dorsal surface of the orthotic a groove which is disposed laterally from the medial arch support of the orthotic such that the groove modulates the ability of the 1st ray of the foot to plantar flex.

2. A shoe orthotic according to claim 1 wherein the groove extends from a point slightly proximal to the mid line of the arch support and extends distally along the dorsal surface of the orthotic to the metatarsal breakline.

3. A shoe orthotic according to claim 1 or claim 2 wherein the depth of the groove relative to the dorsal surface is greatest in a portion distal to the mid line of the arch support and the width of the groove tapers outward from the proximal end of the groove to the distal end of the groove.

4. A shoe orthotic according to any one of claims 1 to 3 wherein there is provided in the dorsal surface an indentation positioned at the head of the 1st metatarsal and continuing under the proximal portion of the proximal phalange such that the indentation modulates the ability of the 1st ray to plantar flex.

5. A shoe orthotic according to claim 4 wherein the indentation is located at the distal end of the groove and is continuous with the groove.

6. A shoe orthotic according to claim 4 or claim 5 wherein the indentation is a bowl-shaped indentation.

7. A shoe orthotic according to claim 6 wherein the bowl-shaped indentation has a diameter which is approximately one third of the width of the orthotic at the distal end of the groove.

8. A shoe orthotic according to any of claims 1 to 3 wherein the orthotic is a three-quarter length orthotic, the distal border of which terminates at the metatarsal break point, wherein a portion of the orthotic at the head of the first metatarsal is cut away such that the cut away portion modulates the ability of the first ray to plantar flex.

9. A shoe orthotic according to any one of claims 1 to 8 wherein there is provided an increase in the declination of the medial dorsal surface distal to the midline of the arch relative to the declination of the lateral dorsal surface distal to the midline of the arch such that the increase in the declination of the medial dorsal surface modulates the ability of the 1st ray to plantar flex.

10. A shoe orthotic according to claim 9 wherein the increase in the declination of the medial dorsal surface is present in a region extending from the midpoint of the arch through to the metatarsal breakline.

11. A shoe orthotic according to any one of claims 1 to 10 wherein there is provided an elevation of the orthotic surface at a point under the cuboid of the foot on the lateral edge of the orthotic such that the elevation modulates the ability of the 1st ray to plantar flex.

12. A shoe orthotic according to any of claims 1 to 11 wherein the shoe orthotic is a pre-form orthotic.

13. An insole of a shoe comprising a dorsal surface and an arch support wherein there is provided in the dorsal surface of the insole a groove which is disposed laterally from the medial arch support of the insole such that the groove modulates the ability of the 1st ray of the foot to plantar flex.

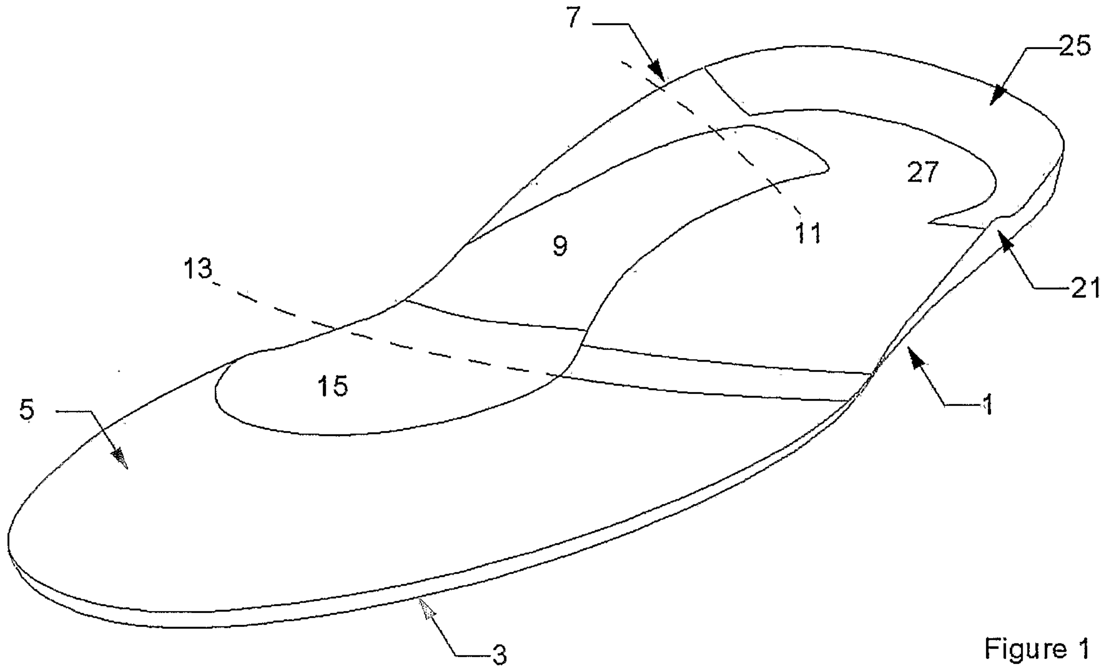

Figure 1

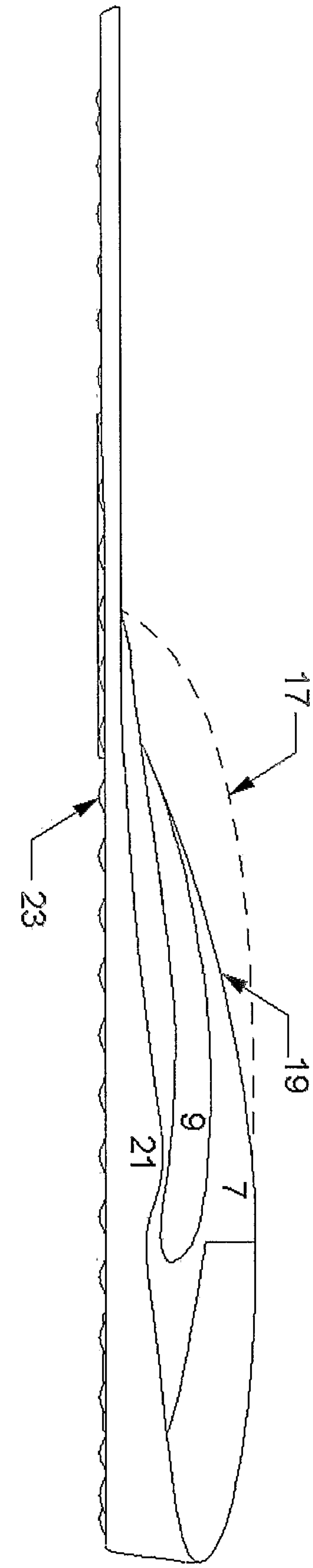

Figure 2

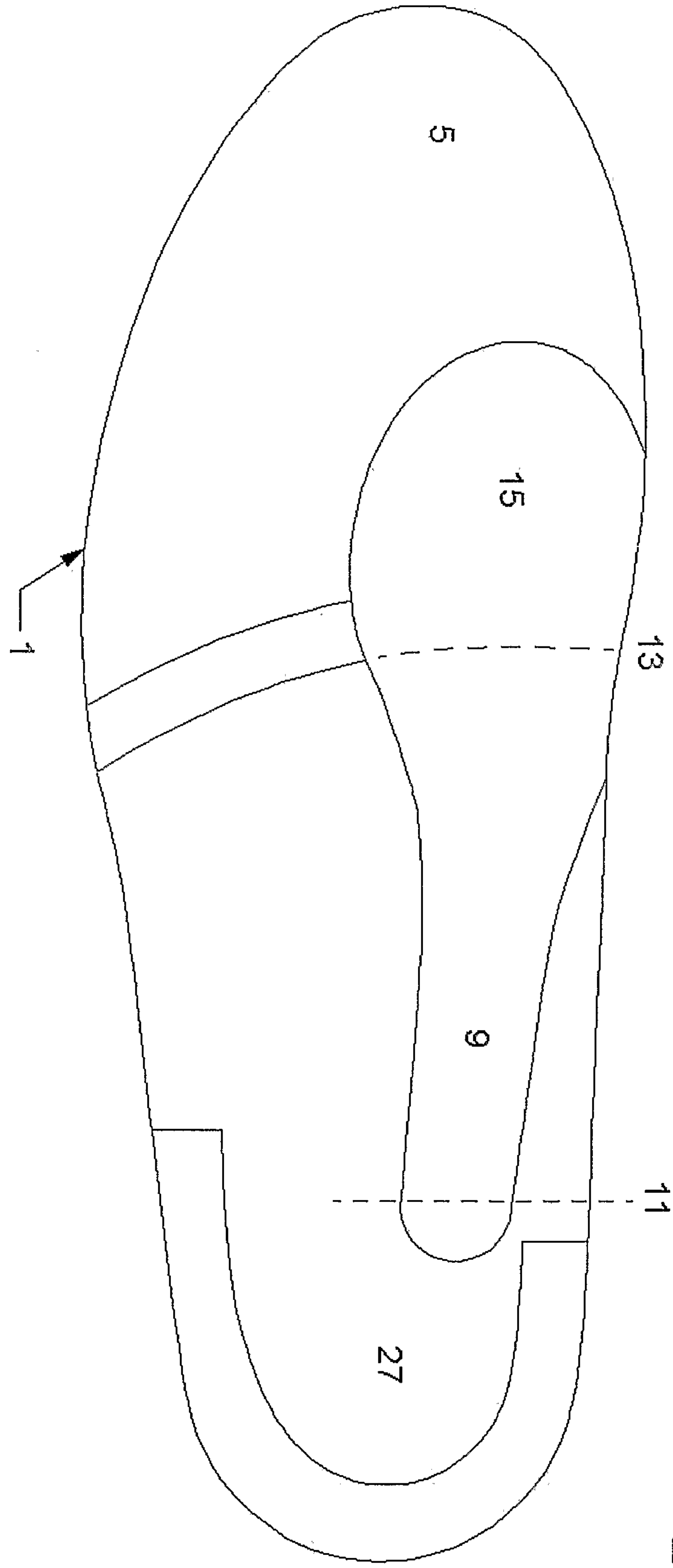

Figure 3

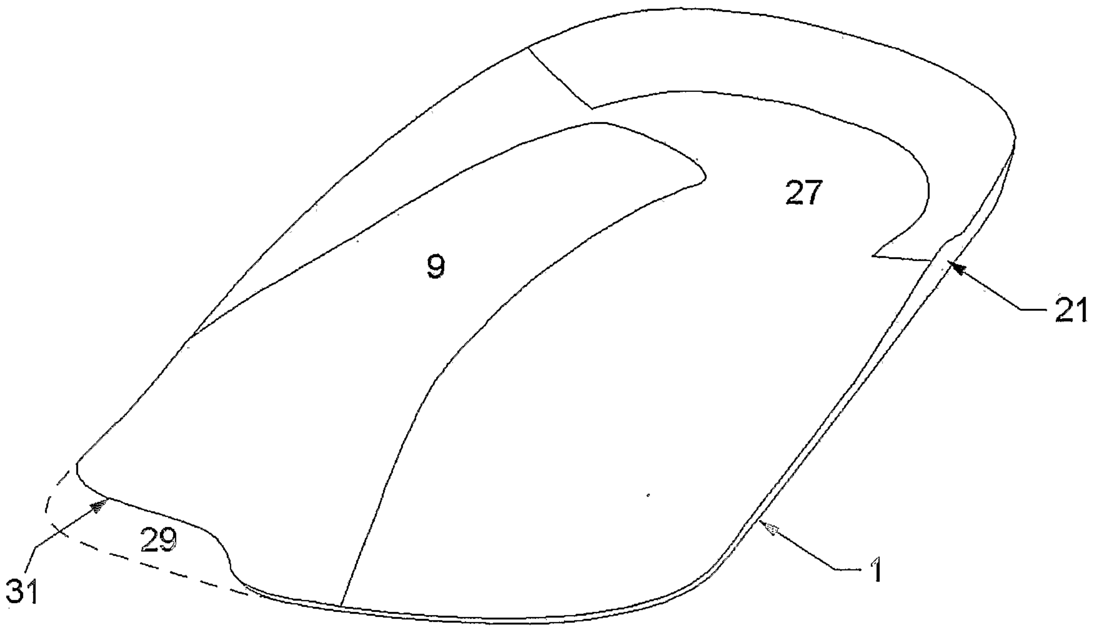

Figure 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/000440

A.	CLASSIFICATION OF SUBJECT MATTER
Int. Cl. 7:	A43 B 7/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI + keywords: orthotic orthosis insole insert groove recess ray arch windlass foot feet shoe and similar terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4756096 A (MEYER) 12 July 1988 Columns 2-11	1-5, 9-11, 13
A	WO 1998018358 A1 (UMBRO EUROPE LTD) 7 May 1998 Whole document	
A	US 5924219 A (HEALY et al) 20 July 1999 Whole document	
A	Hicks JH: The mechanics of the foot II - The plantar aponeurosis and the arch. Journal of Anatomy 88: 25-31 1954	

☐ Further documents are listed in the continuation of Box C ☒ See patent family annex

* Special categories of cited documents:

"A"	document defining the general state of the art which is not considered to be of particular relevance	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E"	earlier application or patent but published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 24 May 2004	Date of mailing of the international search report 27 MAY 2004
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer **Sue Thomas** Telephone No : (02) 6283 2454

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Patent Document Cited in Search Report		Patent Family Member					
US	4756096	CA	1266377	US	4669142		
WO	9818358	BR	9712444	CN	1233943	EP	0934008
US	5924219						

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX