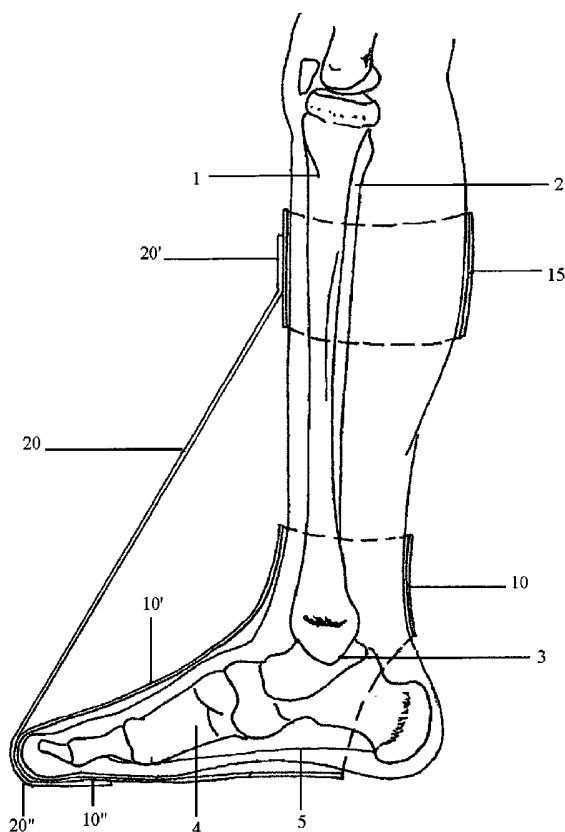


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(57) Abstract: A device for a subject having plantar fasciitis, the device comprising: (a) an elastic sock (10), (b) a leg binding (15) and (c) an elastic strap (20), wherein in use the elastic strap extends from adjacent a toe portion of the elastic sock to the leg binding so as to restrain the plantar fascia from flexion, yet permits the subject to walk and exercise the plantar fascia.





For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Plantar-Flexion Restraint Device

Field of the Invention

The present invention relates to a device for restraining plantar flexion. In particular it relates to a device for restraining plantar flexion in a person having inflammation or other
5 disorder of the plantar fascia. More particularly the present invention relates to a restraint device for restraining contraction of the plantar fascia, preferably keeping the plantar fascia in a neutral to slight dorsiflexion by passive static tension.

Background of the Invention

In this specification where a document, act or item of knowledge is referred to or
10 discussed, this reference or discussion is not an admission that the document, act or item of knowledge or any combination thereof was at the priority date, publicly available, known to the public, part of the common general knowledge or known to be relevant to an attempt to solve a problem with which this specification is concerned.

While the present invention will be described with particular reference to the disorder
15 known as 'heel spur' the invention is not so limited but relates more generally to disorders or inflammation of the plantar fascia.

The plantar fascia (also known as the plantar aponeurosis) is a thick fibrous material that covers the soft tissue on the sole of the foot, providing static support for the medial longitudinal arch of the foot. The plantar fascia originates at the heel (specifically, at the
20 medial tuberosity of the calcaneus), spreads out over the sole of the foot and terminates in the ligaments near the tarsal heads in the forefoot. In use it helps to restrain motion with in the joints of the ankle and forefoot.

The plantar fascia can become inflamed as a result of stress caused by overuse or as a result of a condition such as heel spur. Heel spurs typically develop as an abnormal
25 growth in the front and bottom of the heel bone due to calcium deposits that form when the plantar fascia pulls away from the heel. Initially, sufferers commonly experience a dull intermittent pain in the heel which may develop into a sharp persistent pain. But it is not the spur that causes pain. The pain is caused by inflammation of the plantar fascia (known as plantar fasciitis). The classic sign of plantar fasciitis is heel pain with the first few steps
30 in the morning. The pain is usually in the front and bottom of the heel, but it can be over

any portion of the bottom of the foot where the fascia plantar is located. The pain varies in intensity from person to person and it can last a few months, become permanent, or come and go. Striking of the heel on the ground can exacerbate the condition, but is not a cause of the inflammation.

- 5 Causes of heel spur and subsequent inflammation of the plantar fascia include inadequate flexibility in the calf muscles, lack of arch support or sole cushioning in footwear, footwear that has inflexible soles, overweight, injury, sudden increase in physical activity, and spending too much time on the feet. Other causes of inflammation of the plantar fascia include arthritis, heel bone damage ("stress fracture"), loss of natural tissue for cushioning
10 under the heel ("fat pad atrophy") and tarsal tunnel syndrome.

- The key to proper treatment of plantar fasciitis is determination of what is causing the excessive stretching of the plantar fascia. However in many cases, finding a specific cause is difficult. Typically, plantar fasciitis is treated with the use of a mixture of approaches as appropriate to the sufferer. These include losing weight, the use of orthotics, increasing
15 cushioning in the sole of shoes, resting the foot, applying supporting tape and wearing of night splints. Application of ice often helps to reduce pain although many sufferers find it necessary to use analgesics such as ibuprofen cream that can be applied directly to painful areas. In more severe cases injections of painkillers may be used. Stretching the calf muscles using exercises that do not re-injure the fascia is a cure for many people.
20 Typically these exercises are performed 3 times a day and especially before getting out of bed in the morning. Surgery may be necessary in extreme cases of plantar fasciitis.

- Orthotic based treatment for plantar fasciitis include elevating the heel with the use of a heel cradle or heel cup. Heel cradles and heel cups provide extra comfort and cushion to the heel, and reduce the amount of shock and shear forces experienced from everyday
25 activities. When the cause of plantar fasciitis is over-pronation (flat feet), an orthotic with rearfoot posting and longitudinal arch support is an effective device to reduce the over-pronation, and allow the condition to heal.

- Many different devices have been developed to treat plantar fasciitis, particularly plantar fasciitis caused by heel spur. One such device for treatment of plantar fascia is described
30 in US patent 5,399,155 (Strassburg et al) and consists of an over the calf sock having a reinforced adjustable support strap attached around the upper portion of the sock with a

“D” ring attached to the front (shin) side. A reinforced inelastic adjustable strap is attached to the toe of the sock, with a hook and loop assembly attached for closure. When this strap is passed through the “D” ring and secured by means of the hook and loop assembly, the plantar fascia can be maintained in the desired position. One of the disadvantages of this type of device, and many other orthotic devices, is that they hold the foot quite rigid so the wearer cannot walk. The device of US-5,399,155 has an inelastic support strap hindering the normal action of the foot and ankle during walking hence use of the device is limited to times when the wearer is asleep or resting. Furthermore, solely treating heel spur by holding the plantar fascia in a neutral position and preventing movement or exercise is unlikely to cure heel spur.

Accordingly there is a need for a device having wider applicability, which can be used when the wearer is mobile as well as when they are sleeping or resting.

Summary of the Invention

The present invention provides a device for a subject having plantar fasciitis, the device comprising

- (1) an elastic sock,
- (2) a leg binding and
- (2) an elastic strap

wherein in use the elastic strap extends from adjacent a toe portion of the elastic sock to the leg binding so as to restrain the plantar fascia from flexion, yet permits the subject to walk and exercise the plantar fascia.

Typically the elastic sock fits over the foot of the wearer in the manner of a gauntlet. It may extend over the ankle of the wearer. In addition it may extend further up the calf to the knee, thus enclosing part or all of the tibia and fibula. The foot may be entirely enclosed or alternatively the sock may include one or more openings. For example the elastic sock may leave the heel exposed. Preferably the sock is of a size that fits snugly around the wearer's foot, ankle and calf. Alternatively the sock may be adjustable around the foot, ankle or calf so that a snug fit can be achieved. For example, the elastic sock may include adjustable straps or tapes. Preferably the elastic sock includes fastening material such as the hook and loop fastener known as Velcro™.

Typically the elastic sock has an upper surface and a lower surface. In use the upper surface of the elastic sock lies adjacent the upper of the foot and the lower surface is adjacent the sole of the foot. The upper and lower surfaces may be integral. For example the upper and lower surfaces may be sewn or adhered together to provide a gauntlet for the
5 wearer's foot.

Typically at least the upper surface or the lower surface of the elastic sock is constructed of flexible material that does not unduly restrict movement of the wearer's foot or ankle when exercising and walking. The flexible material may for example comprise a polymeric material such as flexible rubberized material, polypropylene or polyurethane. The elastic
10 sock may consist of layers of different material.

The upper surface and lower surface of the elastic sock may be of the same, or different material. In a preferred embodiment the upper surface is comprised of polymeric material such as flexible rubberized material, polypropylene or polyurethane while the lower surface comprises a non-slip material to assist traction and avoid slipping as the wearer
15 walks. For example, the lower surface may comprise flexible material coated with synthetic rubber having a raised pattern to improve the non-slip characteristics of the coating.

The elastic nature of the sock has the advantage of stimulating blood flow to the wearer's calf and foot, in contrast to many of the devices of the prior art that hold the foot and calf
20 rigid or under compression so that blood flow is restricted and the natural recuperative functions of the body are inhibited. Preferably the elastic sock has thermotherapeutic properties, that is, it keeps the enclosed tissue warm so that blood flow, and thus healing are stimulated.

The principal function of the leg binding is to provide an anchor point on the wearer's leg
25 for one end of the elastic strap. The leg binding may be integral with the elastic sock or it may be separate from the elastic sock. The leg binding may be located adjacent any part of the wearer's leg such as the ankle, or intermediate the ankle and the knee.

In one embodiment the leg binding is integral with the elastic sock, attached to the elastic strap by stitching or the like.

30 In another embodiment the leg binding is not integral with the elastic sock but can be removably attached. For example the leg binding may comprises a strip of material that

can be wrapped around the calf or ankle of the wearer, held closed by hook and loop material fastening such as VelcroTM. The elastic strap can be attached to the leg binding by Velcro or by a buckle.

5 The leg binding may be of any convenient length and width. Preferably the leg binding can be adjusted to ensure a snug fit around the calf or ankle so that the device does not move or become displaced when the wearer moves.

The leg binding is typically constructed of flexible material that does not unduly restrict movement of the wearer's foot or ankle. The leg binding may comprise the same material as the elastic sock, or it may comprise different material.

10 The elastic strap may comprise elastic material along its entire length that allows stretching in a longitudinal direction. Alternatively it may comprise elastic material along part of its length. Typically the ends of the elastic strap are reinforced with stronger material for attachment to the elastic sock and leg binding.

15 The elastic strap in combination with the rest of the device resists contraction of the plantar fascia when the wearer is at rest, preferably keeping the plantar fascia in a neutral to slight dorsiflexion by passive static tension, yet allow movement of the foot relative to the calf and ankle so that the wearer can walk when they want to or perform exercises that assist reduction of inflammation of the plantar fascia. For example, the wearer may wish to carry out exercises that stretch the calf muscle but do not re-injure the plantar fascia.

20 In use the elastic strap extends from the region of the elastic sock adjacent the wearer's toe to the leg binding. The elastic strap may be attached to the upper surface or the lower surface, or both surfaces of the elastic sock. Typically one end of the strap is integral with the lower surface of the elastic sock. Preferably it is attached to the part of the lower surface which lies under the toes of the wearer or near the ball of the foot. The end of the
25 strap is typically attached to the elastic sock by adhesive or stitching.

The other end of the elastic strap may be integral with the leg binding, but more typically, it is removably attached to the leg binding by hook and loop material fastening such as Velcro. In another embodiment, the other end of the elastic strap is removably attached to the leg binding by a buckle, or plastic loop. The end of the binding may include Velcro so that it
30 can be passed through the plastic loop and fastened to itself using the Velcro.

Preferable the end of the elastic strap adjacent the leg binding is adjustable so the overall length of the elastic strap can be modified in order to maintain static tension on the plantar fascia.

Drawings

- 5 The invention will now be further described with reference to the following non-limiting drawings:

Figure 1a shows a cross sectional view of a foot and ankle located in a device according to one embodiment of the present invention,

- 10 Figure 1b shows a cross sectional view of a foot and ankle located in a device according to another embodiment of the present invention,

Figure 2 shows a further embodiment of a device according to the present invention depicted in two different foot positions,

Figure 3 shows a further embodiment of a device according to the present invention on a wearer who is walking;

- 15 Figure 4 shows a cross sectional view of a further device according to the present invention;

Figure 5 shows a cross sectional view of a further device according to the present invention;

Figure 6 shows a perspective view of the device of Figure 1a when removed from the foot of the wearer.

- 20 Figure 1a shows a foot, ankle and calf located in a device (shown in cross section) according to one embodiment of the present invention. The foot is depicted in x-ray view to show the tibia (1), the fibula (2), the ankle (comprising the ends of the tibia and fibula, plus the talus underneath) (3), the foot bones (4) and the plantar fascia (5). The ankle joint is responsible for up and down motion of the foot.

- 25 In this view the foot is located within an elastic sock (10) that partially encloses the foot and ankle and encircles the lower part of the tibia and fibula, leaving the heel uncovered. The elastic sock (10) has an upper surface (10') adjacent the upper of the foot and a lower surface (10'') adjacent the sole of the foot.

The leg binding (15) encircles the upper part of the tibia (1) and fibula (2). The elastic strap (20) is attached by Velcro at one end (20') to the leg binding (15) and attached by

stitching at the other end (20'') to the lower surface (10'') of the elastic sock (10) near the ball of the foot.

Figure 1b shows a foot, ankle and calf located in a device (shown in cross section) according to a further embodiment of the present invention. In this view the foot is located within an elastic sock (10) having an upper surface (10') comprising a flexible polymeric material and a lower surface (10'') comprising a flexible polymeric material having non-slip surface to improve the traction between the sole of the wearer's foot and the surfaces on which the wearer may walk.

The leg binding (15) encircles the upper part of the calf, just below the knee. The elastic strap (20) is attached at one end by stitching to the upper surface (10') of the elastic sock (10) and at the other end to the leg binding (15). Intermediate the two ends of the strap is a plastic loop (21) which can be used to adjust the length of the elastic strap (20).

Specifically the elastic strap (20) comprises two parts (23, 24), each of which has a free end. The free ends are passed through the plastic loop (21), and releasably secured back on themselves by Velcro. The wearer can thus adjust the length of the elastic strap (20) and control the amount of passive static tension imposed on the plantar fascia.

Figure 2 shows a further embodiment of the device of the present invention when in use, in two different positions. The device shown is similar to that shown in Figure 1, except that the end (20') of the elastic strap (20) comprising Velcro is attached to the leg binding (15) by a plastic loop (22). The end (20') of the elastic strap is threaded through the loop (21) and fastened back on the elastic strap (20) by Velcro hook and loop fastening. This type of fastening provides a convenient means for adjusting the length of the elastic strap (20).

Figure 2 shows the leg of a subject wearing the device when their foot is flat on the ground (Figure 2a) and when they stand on tiptoe (Figure 2b). The elastic strap has sufficient stretch to maintain static tension on the plantar fascia when the foot is at rest, as well as allowing movement of the foot relative to the calf.

Figure 3 shows a further embodiment of the device according to the present invention on the left and right legs of a wearer who is walking. In this embodiment the leg binding (15) encircles the part of the elastic sock (10) that is located adjacent the ankle of the wearer.

Figure 4 shows a plan view of a further embodiment of the device of the present invention. In this embodiment the device is the same as that shown in Figure 3 except that the heel is enclosed. The elastic sock (10) is an appropriate size for the wearer and in this embodiment

the fit is non-adjustable. The sock is sufficiently elastic that it fits snugly to the form of the foot. The leg binding (15) is a strip of elastic material that snugly encircles the wearer's ankle or lower calf region and the ends of the strip are attached together by Velcro. The elastic strap (20) is attached at one end (20') to the lower portion of the elastic sock, and at the other end
5 (20') to the part of the leg binding (15) adjacent the front of the wearer's shin.

Figure 5 shows a plan view of a further embodiment of the device of the present invention. In this embodiment the device is the same as that shown in Figure 3 except that the leg binding (15) is integral with, and forms a portion of the elastic sock (10).

Figure 6 shows the device of Figure 1 removed from the foot of the wearer. The elastic
10 sock (10) is comprised of flexible rubberized material lined with absorbent cloth and comprises an upper portion (10') and a lower portion (10'') held together by several lines of stitching (11). The elastic sock (10) encloses the foot (including the phalanges, metatarsals and area intermediate the metatarsals and the talus) and the ankle (including the lower part of the tibia and fibula). The binding is shaped such that in use the calcaneus
15 (heel bone) of a wearer would be left exposed. The part of the elastic sock that encircles the ankle comprises a strip (30) that includes a patch of micro hooks at its free end (31) that in use can be removably attached to a patch of micro loops (32) located on the outer surface of the front of the elastic sock. The fit of the elastic sock can thus be adjusted by appropriately fitting together the two Velcro patches (31 and 32).

20 In this embodiment the leg binding (15) is a strip of elastic material that includes micro hooks (16) on the outer surface of one of its free ends and micro loops (17) on the inner surface of the other free end.

The elastic strap (20) has one end (20'') integral with the lower portion (10'') of the elastic sock (10), held in place by stitching. The other end (20') is threaded through a plastic loop
25 (22) anchored to the front of the leg binding (15). The end (20') of the elastic strap (20) comprises micro hooks and micro loops and is thus fastened to itself. This end (20') can be used to adjust the length of the elastic strap between the elastic sock (10) and the leg binding (15).

The word 'comprising' and forms of the word 'comprising' as used in this description does not
30 limit the invention claimed to exclude any variants or additions.

Modifications and improvements to the invention will be readily apparent to those skilled in the art. Such modifications and improvements are intended to be within the scope of this invention.

CLAIMS

The claims defining the invention are as follows:

1. A device for a subject having plantar fasciitis, the device comprising
 - (a) an elastic sock,
 - (b) a leg binding and
 - (c) an elastic strapwherein in use the elastic strap extends from adjacent a toe portion of the elastic sock to the leg binding so as to restrain the plantar fascia from flexion, yet permits the subject to walk and exercise the plantar fascia.
2. A device according to claim 1 wherein in use, the device resists contraction of the plantar fascia when the subject is at rest.
3. A device according to claim 1 or claim 2 wherein in use, the device keeps the plantar fascia in a neutral to slight dorsiflexion by passive static tension, yet allows movement of the foot relative to the calf and ankle.
4. A device according to any one of the previous claims wherein the elastic sock extends over the ankle of the wearer and encloses at least part of the subject's tibia and fibula.
5. A device according to any one of the previous claims wherein the elastic sock includes one or more openings.
6. A device according to any one of the preceding claims wherein the elastic sock further includes straps or tapes for adjusting the fit of the elastic sock to the subject's foot.
7. A device according to any one of the preceding claims wherein the elastic sock has an upper surface and a lower surface, which surfaces are integral.
8. A device according to claim 7 or claim 8 wherein the lower surface of the elastic sock includes a non-slip material.
9. A device according to any one of the preceding claims wherein the leg binding is integral with the elastic sock.

10. A device according to any one of the previous claims wherein one end of the elastic strap is integral with the elastic sock.
11. A device according to any one of the preceding claims wherein in use, the leg binding is located adjacent the subject's ankle.
12. A device according to any one of claims 1 to 12 wherein in use the leg binding is located intermediate the ankle and knee of the subject.
13. A device according to any one of the previous claims wherein the leg binding can be wrapped around the calf or ankle of the wearer, held closed by hook and loop material fastening.
14. A device according to any one of the previous claims wherein one end of the elastic strap is located adjacent the leg binding and is adjustable so the overall length of the elastic strap can be modified in order to maintain static tension on the plantar fascia.
15. A device according to any one of the preceding claims wherein the elastic sock is entirely made of flexible material.
16. A device according to any one of the preceding claims wherein the leg binding is entirely made of flexible material.
17. A device according to any one of the preceding claims wherein the elastic strap is entirely made of flexible material.
18. A device according to any one of claims 15 to 17 wherein the flexible material is a polymeric material or a combination of polymeric materials.
19. A device according to any one of claims 15 to 17 wherein the flexible material is chosen from group comprising neoprene, flexible rubberized material, polypropylene or polyurethane.
20. A device according to any one of claims 15 to 17 wherein the flexible material has thermotherapeutic properties.
21. A device according to any one of the preceding claims which stimulates blood flow to the subject's calf and foot.
22. A device according to claim 1 and substantially as herein described with reference to the drawings.

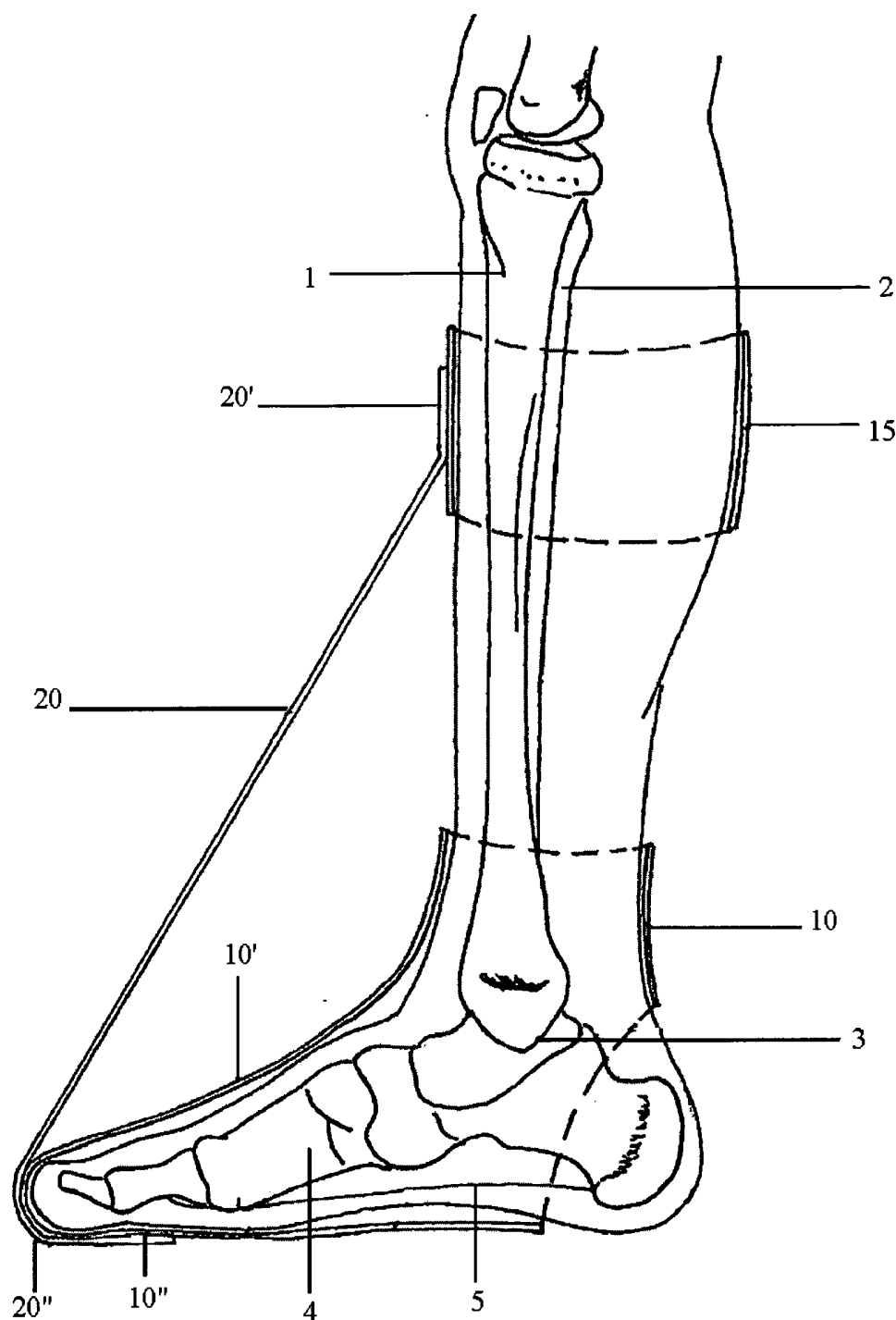


FIGURE 1A

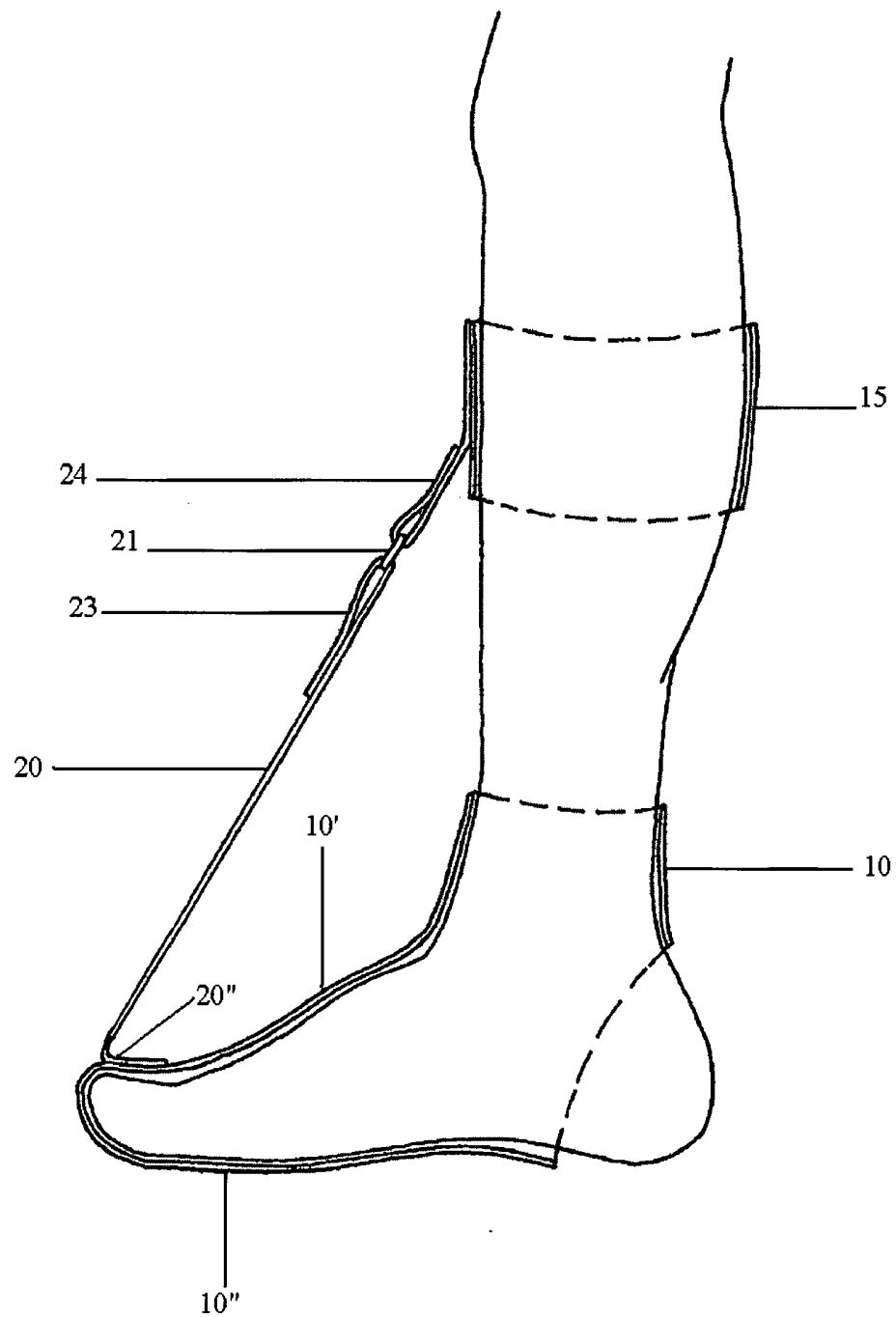


FIGURE 1B

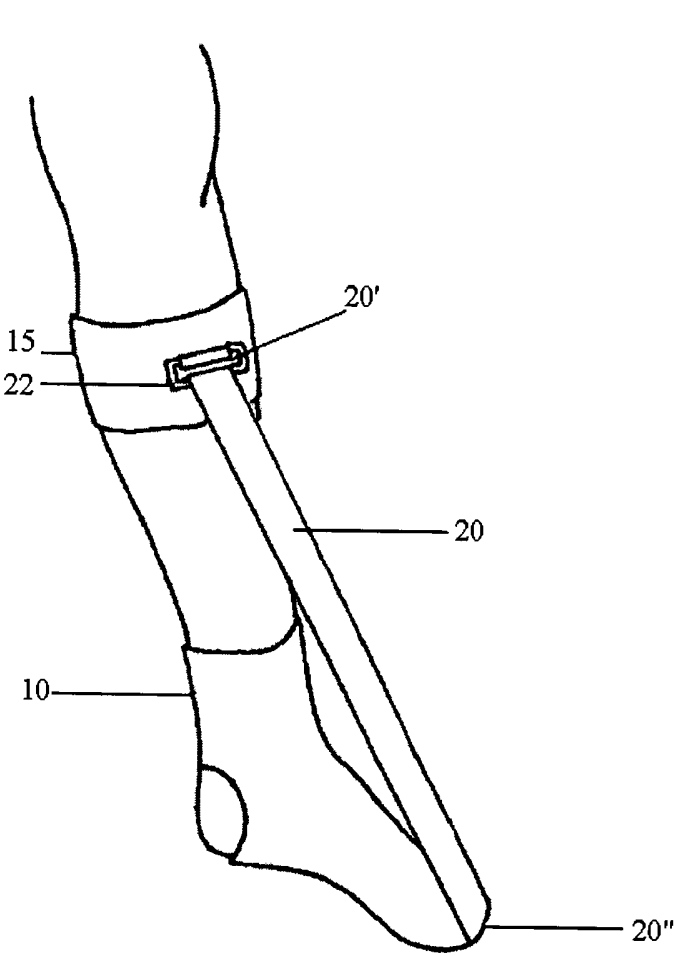


FIGURE 2A

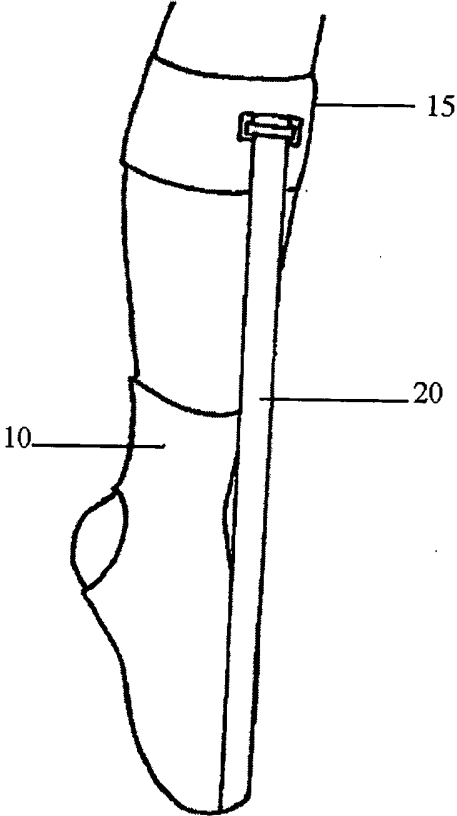


FIGURE 2B

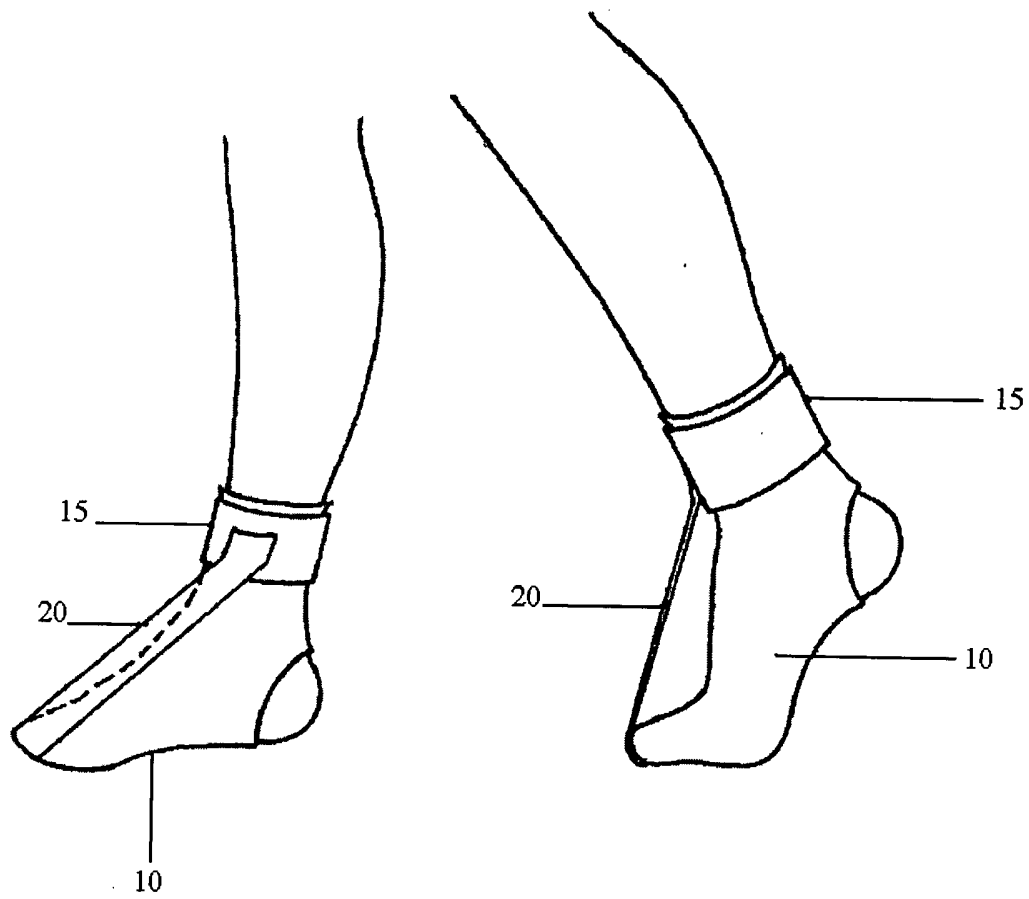


FIGURE 3

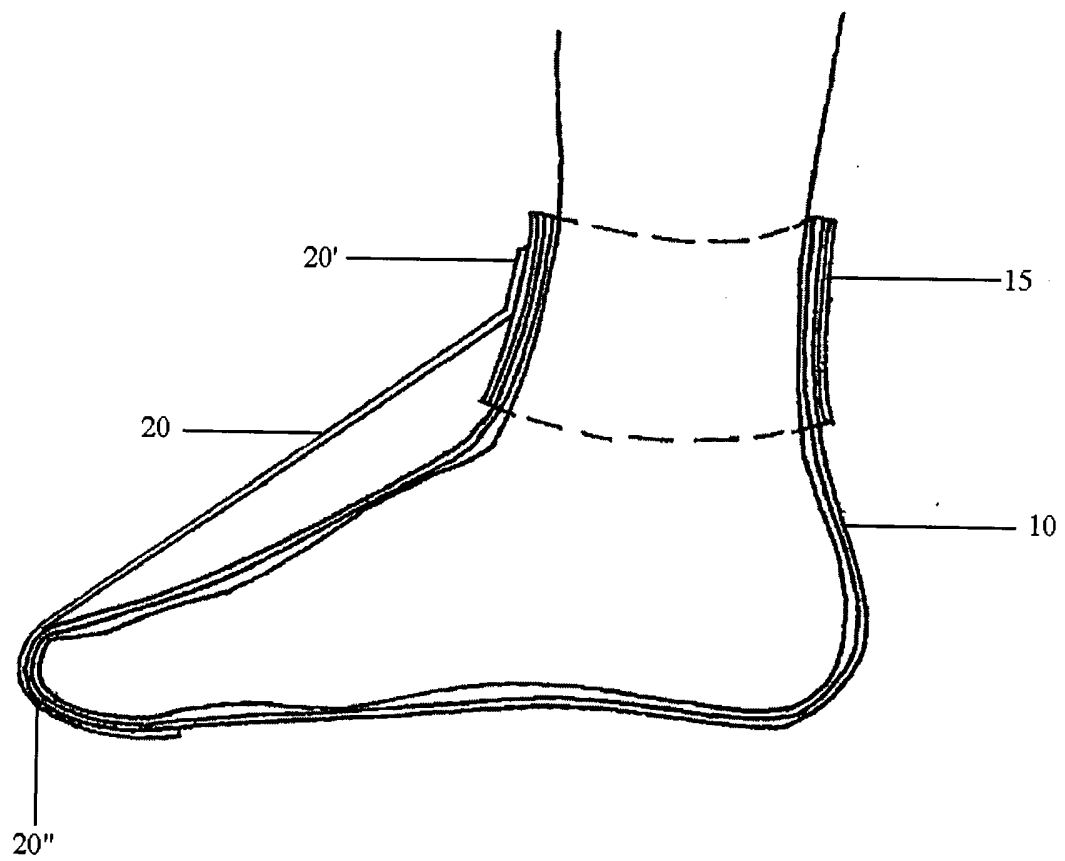


FIGURE 4

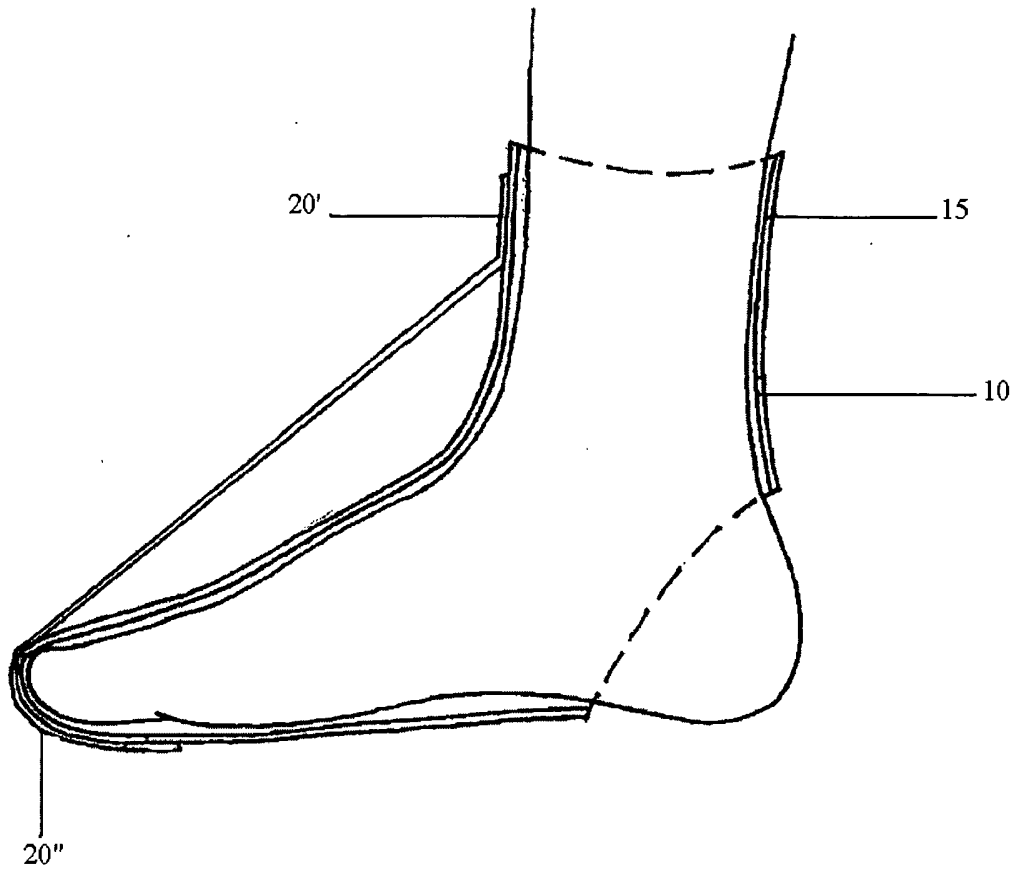


FIGURE 5

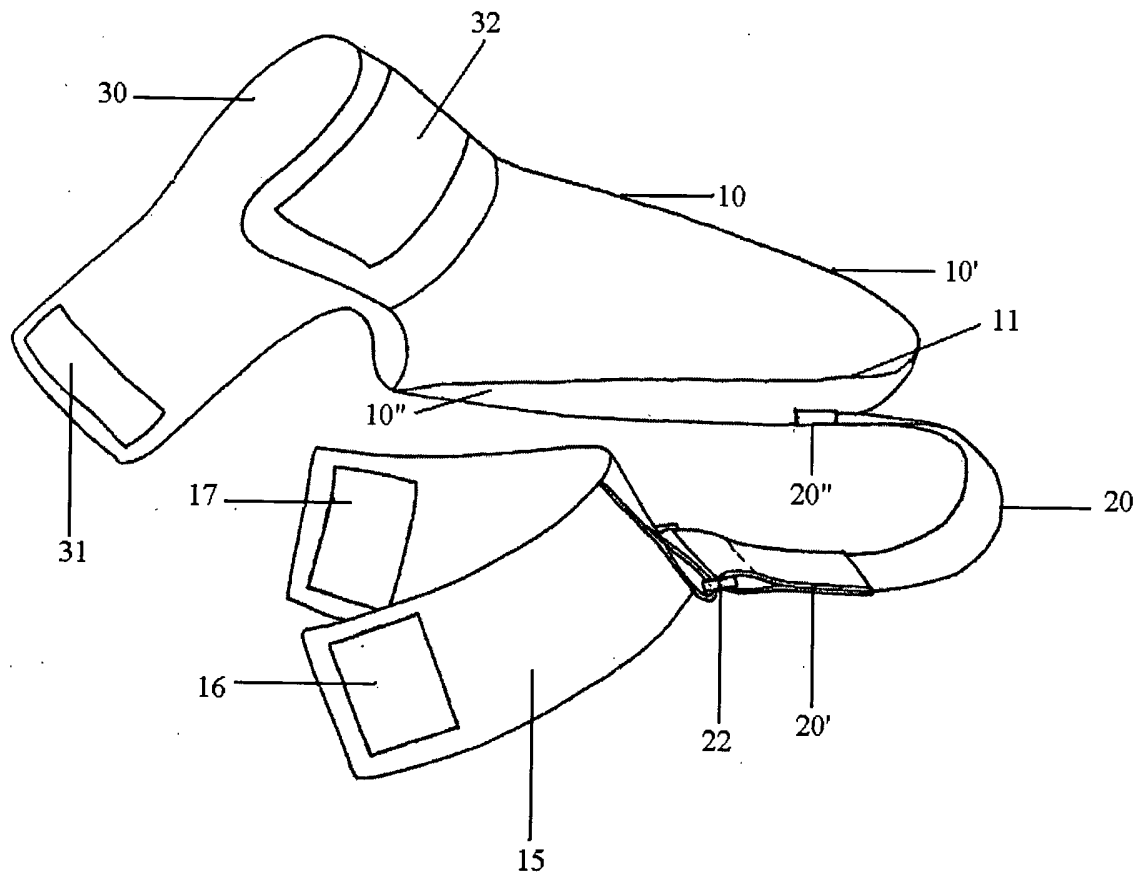


FIGURE 6

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2005/001108

A. CLASSIFICATION OF SUBJECT MATTER Int. Cl. ⁷ : A61F 5/00, A61F 5/37 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, USPTO, eSPACE (IPC: A61F 5/- ; KEYWORDS: plantar, fasci+, flexion, restrain+, immob+, restrict+, limit+, sock+, boot+, gauntlet+, strap+, bind+, tape+, band+)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6695797 B2 (TRIELOFF) 24 February 2004 See figure 2 and item 40.	1 to 22
X	US 5486157 A (DiBENEDETTO) 23 January 1996 See figure 1 and item 40.	1 to 22
X	US 5399155 A (STRASSBURG et al.) 21 March 1995 See figure 1 and item B.	1 to 22
X	US 5382224 A (SPANGLER) 17 January 1995 See figure 3 and item 7.	1 to 22
☒ 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 "E" earlier application or patent but published on or after the international filing date "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) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"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 "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 "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 "&" document member of the same patent family	
Date of the actual completion of the international search 8 August 2005		Date of mailing of the international search report 17 AUG 2005
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929		Authorized officer PETER T. WEST Telephone No : (02) 6283 2108

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2005/001108

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4566447 A (DEIS) 28 January 1986 See figures 1, 2, 6 and column 3 lines 55 to 59.	1 to 22
X	US 4329982 A (HEANEY) 18 May 1982 See figures 1, 2 and column 3 line 54.	1 to 22

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2005/001108

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Member
US 6695797	US 2002129821
US 5486157	
US 5399155	
US 5382224	
US 4566447	
US 4329982	
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.	
END OF ANNEX	