

(12) STANDARD PATENT
(19) AUSTRALIAN PATENT OFFICE

(11) Application No. **AU 2001237504 B2**

(54) Title
Placebo-type compression orthosis

(51)⁷ International Patent Classification(s)
A61F 013/08

(21) Application No: **2001237504** (22) Date of Filing: **2001.02.27**

(87) WIPO No: **WO01/64152**

(30) Priority Data

(31) Number	(32) Date	(33) Country
00 02527	2000.02.29	FR

(43) Publication Date: **2001.09.12**

(43) Publication Journal Date: **2001.11.22**

(44) Accepted Journal Date: **2005.06.16**

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(56) Related Art
FR 2588890
FR 2654925
US 4422307
US 4172456
FR 2017339
FR 1122832

(12) DEMANDE INTERNATIONALE PUBLIÉE EN VERTU DU TRAITÉ DE COOPÉRATION
EN MATIÈRE DE BREVETS (PCT)

(19) Organisation Mondiale de la Propriété
Intellectuelle
Bureau international



(43) Date de la publication internationale
7 septembre 2001 (07.09.2001)

PCT

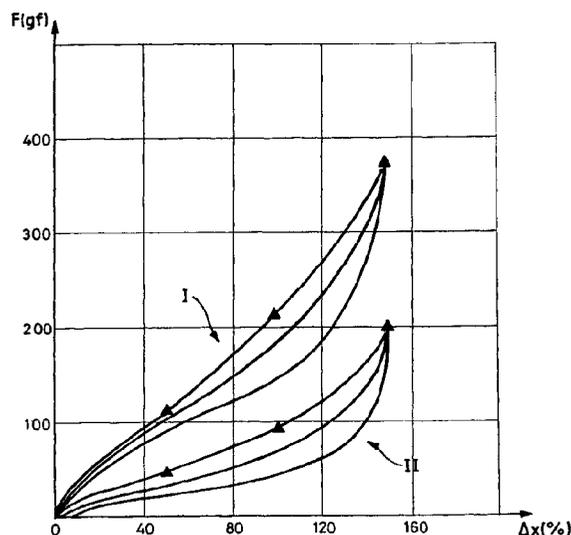
(10) Numéro de publication internationale
WO 01/64152 A1

- (51) Classification internationale des brevets⁷ : A61F 13/08 (71) Déposant (pour tous les États désignés sauf US) : IN-NOTHERA TOPIC INTERNATIONAL, SOCIÉTÉ ANONYME [FR/FR]; 7-9, avenue François Vincent Raspail, F-94110 Arcueil (FR).
- (21) Numéro de la demande internationale : PCT/FR01/00567
- (22) Date de dépôt international : 27 février 2001 (27.02.2001) (72) Inventeurs; et (75) Inventeurs/Déposants (pour US seulement) : GROS-JEAN, Eric [FR/FR]; 8, place Jeanne d'Arc, F-88000 Epinal (FR). MATHIEU, Joël [FR/FR]; 13, rue du Plateau, F-88510 Eloyes (FR). GARDON-MOLLARD, Christian [FR/FR]; 7, avenue de Royat, F-63400 Chamalières (FR).
- (25) Langue de dépôt : français
- (26) Langue de publication : français
- (30) Données relatives à la priorité : 00/02527 29 février 2000 (29.02.2000) FR (74) Mandataire : DUPUIS-LATOURE, Dominique; Cabinet Bardhle, Pagenberg, Dost, Altenburg, Geissler, Isenbruck, 14, boulevard Malesherbes, F-75008 Paris (FR).

[Suite sur la page suivante]

(54) Title: PLACEBO-TYPE COMPRESSION ORTHESIS

(54) Titre : ORTHESE DE CONTENTION DE TYPE PLACEBO



WO 01/64152 A1

(57) Abstract: The invention concerns a medical stocking knitted with a knitting thread having extensible weft inlay, of the placebo type capable of exerting a compression value at the ankle less than 8 mmHg, preferably less than 5 mmHg. It is designed for double blind versus placebo tests with a product having the same structure, the same visual appearance and the same feel as an active stocking but insignificant compression and a thigh/ankle degression close to a single unit. The weft inlay thread has a linear density ranging between 250 and 600 dtex, preferably between 350 and 500 dtex, with an elastic material proportion less than 25 %, preferably less than 20 %, of the total yarn count. Its elongation capacity ranges between 200 and 350 %, preferably between 200 ad 300 %, but its liveliness (II) is very different from that of a support stocking (I) weft inlay thread.

(57) Abrégé : Le bas médical, réalisé par tricotage d'un fil de tricot combiné à un fil de trame extensible, est un bas de type placebo apte à exercer au niveau de la cheville une pression de contention inférieure à 8 mmHg, de préférence inférieure à 5 mmHg. Il est destiné à des essais *versus*

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(81) **États désignés (national)** : AE, AG, AL, AU, BA, BB, BG, BR, BZ, CA, CN, CR, CU, CZ, DM, DZ, EE, GE, HR, HU, ID, IL, IN, IS, JP, KP, KR, LC, LK, LR, LT, LV, MA, MG, MK, MN, MX, NO, NZ, PL, RO, SG, SI, SK, TR, TT, UA, US, UZ, VN, YU, ZA.

MC, NL, PT, SE, TR), brevet OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Publiée :

— avec rapport de recherche internationale

(84) **États désignés (régional)** : brevet ARIPO (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), brevet eurasien (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), brevet européen (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU,

En ce qui concerne les codes à deux lettres et autres abréviations, se référer aux "Notes explicatives relatives aux codes et abréviations" figurant au début de chaque numéro ordinaire de la Gazette du PCT.

placebo en double insu avec un produit ayant la même structure, le même aspect visuel et le même toucher qu'un bas actif mais une compression négligeable et une dégressivité cuisse/cheville voisine de l'unité. Le fil de trame présente une masse linéique comprise entre 250 et 600 dtex, de préférence entre 350 et 500 dtex, avec une proportion de matériau élastique inférieure à 25 % de préférence inférieure à 20 %, du titre total du fil. Sa capacité d'élongation est comprise entre 200 et 350 %, de préférence entre 200 et 300 %, mais sa nervosité (II) est très différente de celle d'un fil de bas de contention (I).

I, Andrew Scott Marland, residing at 35, avenue Chevreul, 92270 Bois-Colombes, France, hereby certify that I am conversant with the French language and am a competent translator thereof into the English language, and that to the best of my knowledge and belief the following is a true and correct translation of French language PCT international application number:

PCT/FR01/00567

Signed this 13th day of September 2002



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SUMMARY OF PARTICULARS OF A FRENCH PCT APPLICATION
=====

Application for:	Patent
Application number:	PCT/FR01/00567
PCT Filing date:	27 FEBRUARY 2001
Name of applicant:	INNOTHERA TOPIC INTERNATIONAL
Form of incorporation:	SOCIETE ANONYME (a form of joint stock company)
Address of applicant:	7-9 avenue François Vincent Raspail F-94110 Arcueil FRANCE
Title:	A COMPRESSIVE ORTHOSIS OF THE PLACEBO· TYPE
Other points (if any):	None.

A COMPRESSIVE ORTHOSIS OF THE PLACEBO TYPE

The invention relates to the field of compressive orthoses for one or both lower limbs, generally known as "elastic stockings" or as "elastic tights".

5 Although the term "stockings" is used below, the invention is not limited to a particular article, but applies equally well to all compressive orthoses, whether in the form of tights, one-legged tights, stockings, or socks.

10 "Elastic stockings" are surgical stockings producing a therapeutic effect by compressing the lower limbs, and they are conventionally distinguished both from "fashion stockings" and from "support stockings" (also known as "anti-fatigue stockings"). Surgical elastic stockings
15 are stockings that exert pressure of more than 10 millimeters of mercury (mmHg) to 36 mmHg as measured at the ankle (equivalent to 13 hectopascals (hPa) to 48 hPa; the present description nevertheless uses mmHg as the unit for measuring pressure, given that this usage is
20 universal in the field of phlebology and medical compression). In addition, elastic stockings exert pressure that decreases going from the ankle towards the thigh.

At the ankle, support stockings exert a pressure of
25 only 6 mmHg to 14 mmHg, while fashion stockings exert a pressure of 1 mmHg to 4 mmHg.

In order to apply a high level of compression on the lower limbs, elastic stockings are made of an elastic material, typically a knit of very tight texture
30 associated with an incorporated elastic weft yarn (generally covered elastane) of large weight per unit length.

That particular structure gives an elastic stocking a visual appearance and feel that are particular and
35 recognizable, and that are very different from those of a support stocking, and a fortiori of a fashion stocking.

One of the objects of the invention is to propose a structure for a knitted product that presents substantially the same shape, the same appearance, and the same feel as a surgical elastic stocking but which, unlike such a stocking, exerts insufficient pressure on the lower limbs to give rise to any significant therapeutic effect.

The purpose of such a product is to constitute a "textile placebo" for clinical tests designed to show the therapeutic effects of surgical elastic stockings, in application of methodology of the "double blind test versus placebo" type, of the kind commonly used for measuring the effect of the active principles used in medication.

One such placebo study is described for example by M. Chauveau and F. Agbomsom in "Force de compression et symptomatologie de l'insuffisance veineuse fonctionnelle des membres inférieurs: efficacité comparée de six degrés de contention" [Compression force and functional venous insufficiency symptomatology of the lower limbs: a comparison of the effectiveness of six degrees of compression], published in *Phlébologie*, 1997; 50: 731-736.

Nevertheless, that study was carried out to show the effectiveness of support stockings which can easily be substituted by placebo stockings in the form of a fashion stocking having the same color and the same texture. Support stockings and fashion stockings are very similar in terms of appearance and feel and are easily substituted for each other while complying with the requirements of a double blind test with crossover.

That is not true of genuine elastic stockings which are very different from support stockings both in appearance and in feel.

A double blind test versus placebo thus requires a product to be available that has the same visual appearance and the same feel as an active stocking but

which provides negligible compression, while nevertheless not being distinguishable a priori from an active stocking either by the patient or by the doctor prescribing the placebo compression, in order to comply with the
5 procedures of a double blind test.

In order to present similar appearance and feel with an elastic stocking, a placebo stocking (plain stitch or micromesh combined with an elastic weft yarn). However unlike an elastic stocking, it must provide pressure at
10 the ankle of less than about 5 mmHg (it has been shown that hemodynamic phenomena begin at about 7 mmHg).

In addition, and preferable, unlike an elastic stocking, a placebo stocking should not be degressive, i.e. pressure at the thigh should be of the same order as
15 pressure at the ankle, typically with a thigh/ankle digressively ratio lying in the range 0.8 to 1.1. Nevertheless, it should be observed that at low pressure values, differences between the ankle and the thigh are often smaller than the precision of test instruments,
20 which makes it difficult in practice to verify accurately the results that are obtained concerning this parameter.

Furthermore for obvious reasons of convenience and manufacturing costs, it is desirable for placebo stockings to be capable of being knitted on the same machines as
25 elastic stockings, without major modification to the programming thereof.

The present invention provides a compressive orthosis such as a surgical stocking made by knitting a knitting yarn (10) together with an extensible weft yarn (12),
30 Characterized in that said weft yarn (12) presents:

- a mass per unit length, measured under no tension, lying in the range 250 dtex to 600 dtex,

- a proportion of elastic material below 25% of the total weight of the yarn, and
- an elongation capacity lying in the range 200% to 350%,

5 whereby the stocking is a placebo type stocking suitable for exerting compressive pressure at the ankle of less than 8 mmHg.

According to various other characteristics of the inventions:

- 10 - the ration of compressive pressures between the thigh and the ankle is less than 125%, and preferably less than 110%;
- the ratio of compressive pressures between the thigh and the ankle is not less than 80%,

15 There follows a description of various examples implementing the invention and given with reference to the accompanying drawings.

Figure 1 shows the general stitch structure for an elastic stocking.

20 Figure 2 is a graph plotting comparative elongation characteristics for a genuine elastic stocking and for a placebo stocking of the invention.

The placebo stocking of the invention is made using a structure as shown in Figure 1, similar to that so a
25 conventional elastic stocking.

This is a structure knitted using a knitting yarn 10, e.g. in plain stitch, and in combination with a weft yarn 12 covered elastane to produce the desired compression.

The invention related to the particular weft yarn 12
30 that is selected, which yarn must ensure that the article is similar in appearance and feel to a conventional elastic stocking, while nevertheless presenting

compression and degressivity properties that are quite different therefrom.

A series of examples are described below implementing various yarns selected to provide properties that are very different.

Example 1

As a reference, a conventional class I (French classification) elastic stocking was made using the following yarns.

The knitting yarn (which is the same in all of the examples below) was a 17 dtex elastane yarn sold under the Lycra trademark (registered by Dupont de Nemours) with a 42/46 strand SFT PA 6.6 covering (i.e. covered in 42 dtex polyamide yarn with false twist in the S direction).

The weft yarn was an elastane yarn with two coverings having the following characteristics:

- a 310 dtex elastane core;
- 1/3.3 stretch;
- lower covering (LC) 1/22/7 ZFT PA 6.6 (1 yarn 22 dtex 7 strands Z direction false twist polyamide 6.6);
- upper covering (UC) 1/22/7 ZFT PA 6.6.

The weight of the resulting yarn was 400 dtex with 62% elastane and 38% polyamide. Its elongation capacity was about 250% to 300%.

The yarn obtained in that way presented an elongation characteristic as plotted at I in Figure 2, where force is plotted as a function of deformation percentage (the characteristic presents a certain amount of natural hysteresis).

The characteristic was measured using a constant-elongation gradient dynamometer on a yarn spiral having a circumference of 2 meters (m) and doubled back eight times (the force exerted on a section of the yarn was thus 1/16th of the force exerted by the dynamometer), with the yarn being stretched to 150%.

The result obtained gives a visual indication of the "springiness" (stiffness) of the yarn, which increases with increasing elastane percentage in the weight of the yarn.

5 Using the two above-described yarns, a stocking was knitted presenting the following characteristics:

- width: 10.7/15/19.5 mm (width respectively at the ankle, at the calf, and at the thigh);

- length: 125/25/68 mm (ditto).

10 After being shaped and dyed in conventional manner, such a stocking provided pressure at the ankle greater than 10 mmHg, with ankle/thigh degressivity of 75%, and thus complied with the specifications for an elastic stocking of class I.

15

Example 2

For reference purposes, a stocking was made having no weft yarn 12. Such a stocking does indeed deliver practically no compressive pressure (about 1 mmHg).

20 However because of the absence of the elastic weft, that fabric is immediately recognizable because of its lack of firmness, being similar to that of a fashion stocking and thus unsuitable for the intended purpose.

Example 3

In this example, attempts were made to reduce the weight of the elastane in proportion to the desired reduction in compressive pressure.

30 Thus, compared with the class I elastic stocking of Example 1 providing pressure at the ankle of 10 mmHg, the weight of the elastane yarn was divided by two with the difference being made up by increasing the proportion of polyamide.

35 An essential condition for obtaining a satisfactory placebo stocking is that it should be made from yarn presenting mass per unit length that is similar to that

of a yarn used for making a conventional elastic stocking, so as to conserve the same visual appearance.

Another condition is that the yarn of the placebo stocking should have elongation capacity that is
5 identical to that of yarn for an elastic stocking so that it can be knitted under the same conditions as said other yarn.

Other things remaining equal, the weft yarn of Example 1 (310 dtex elastane core having a weight at rest
10 of 400 dtex) was replaced by yarn having the following composition:

- 156 dtex elastane core;
- 1/2.65 stretch;
- 1/33/20 FT PA 6.6 LC;
- 15 - 1/33/20 FT PA 6.6 HC.

The stocking was knitted in identical manner as before.

After shaping and dyeing, pressure measured at the ankle was 5.2 mmHg and pressure at the thigh was
20 3.72 mmHg, giving degressivity of 71%.

The stocking made in this way was satisfactory in terms of pressure at the ankle, but not satisfactory in terms of degressivity, being too far removed from the ideal value of 100% (in practice it is considered that
25 the value should lie in the range 0.8 to 1.1 in order to be satisfactory).

Tests were performed by varying the stretch of the 150 dtex elastane yarn, but they did not enable a satisfactory result to be obtained. By reducing the
30 value of the stretch to 1/2.5, the elongation capacity of the yarn is no longer satisfactory for it to be practical to make a pair of tights.

Example 4

35 To mitigate the limitations mentioned above, the weight of the elastane yarn was reduced further.

In this example, the following composition was selected for the weft yarn:

- 78 dtex elastane core;
- 1/3.5 stretch;
- 5 - 2/33/20 FT PA 6.6 LC;
- 2/33/20 FT PA 6.6 HC.

Such a yarn presented mass per unit length at rest of 480 dtex, thus presenting an elastane content of 16%.

The elongation characteristic of that yarn is given at II in Figure 2, which shows the large difference in springiness compared with a yarn for a class I elastic stocking (characteristic I in Figure 2).

This yarn was used to knit a stocking having width of 9.4/13.2/16.3 mm.

15 After shaping and dyeing, that stocking provided pressure at the ankle of 4.9 mmHg and at the thigh of 2.7 mmHg, so its degressivity was 55%.

Since this degressivity value was still unsatisfactory, its width was modified to values of 20 10.5/14/17 mm. After shaping and dyeing the pressure measured at the ankle was 3.7 mmHg and at the thigh 2.4 mmHg, giving degressivity of 65%.

Another test was performed using the same yarn and the same width values as above, but with shaping and 25 without dyeing: pressure at the ankle was then 2.8 mmHg and degressivity 118%.

Another test was performed by modifying the width at the calf and at the thigh giving width dimensions of 10.5/12.6/15.9 mm. After shaping and prior to dyeing 30 pressure at the ankle was 3.9 mmHg and degressivity was 74%. After dyeing pressure at the ankle was 3.0 mmHg and degressivity 103%.

Finally adding a softening agent after dyeing changed the above parameters slightly: with 6% softening agent 35 (as compared with 1.5% in a normal method) pressure at the ankle was reduced to 2.8 mmHg and degressivity to 87%.

Those various tests show that once the weft yarn has been selected on the basis of the criteria given above, it is possible to obtain fine adjustment for the values obtained for pressure at the ankle and for degressivity
5 by acting on various parameters such as ankle/calf/thigh knitting widths, shaping temperature, dyeing parameters, adding a softening agent and concentration thereof, etc.

In any event, in order to retain a mass per unit length close to that of an elastic stocking yarn with
10 comparable elongation capacity, it appears to be necessary to vary the springiness of the yarn, and in particular it should be reduced in order to ensure that the stocking is ineffective in providing hemodynamic therapy.

15 The weight of the elastane core could indeed be reduced further, e.g. by selecting a 44 dtex core with double covering, each covering yarn itself being made up of two 78 dtex polyamide yarn.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1/A compressive orthosis such as a surgical stocking made
by knitting a knitting yarn (10) together with an
5 extensible weft yarn (12),

Characterized in that said weft yarn (12) presents:

- a mass per unit length, measured under no tension,
lying in the range 250 dtex to 600 dtex,
- a proportion of elastic material below 25% of the
10 total weight of the yarn, and
- an elongation capacity lying in the range 200% to
350%,

whereby the stocking is a placebo type stocking suitable
for exerting compressive pressure at the ankle of less
15 than 8 mmHg.

2/ The orthosis of claim 1, in which the weft yarn (12)
presents a mass per unit length, measured under no
tension, lying in the range 350 dtex to 500 dtex.

20

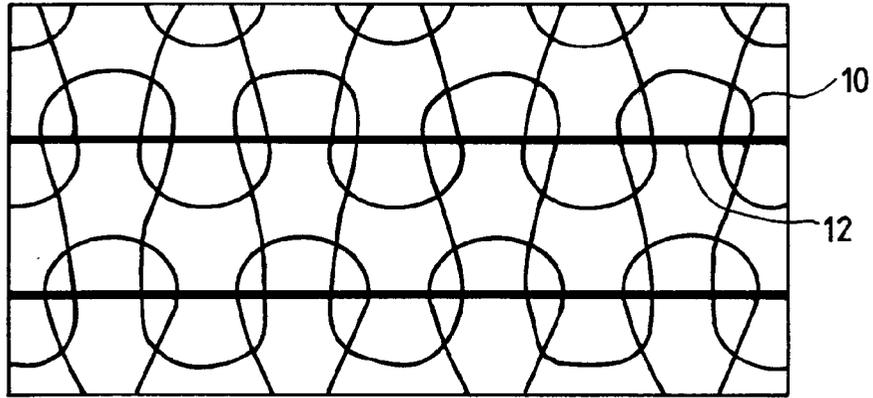
3/ The orthosis of claim 1, in which the weft yarn (12)
present a proportion of elastic material below 20% of the
total weight of the yarn.

25 4/ The orthosis of claim 1, in which the weft yarn (12)
presents elongation capacity lying in the range 200% to
300%.

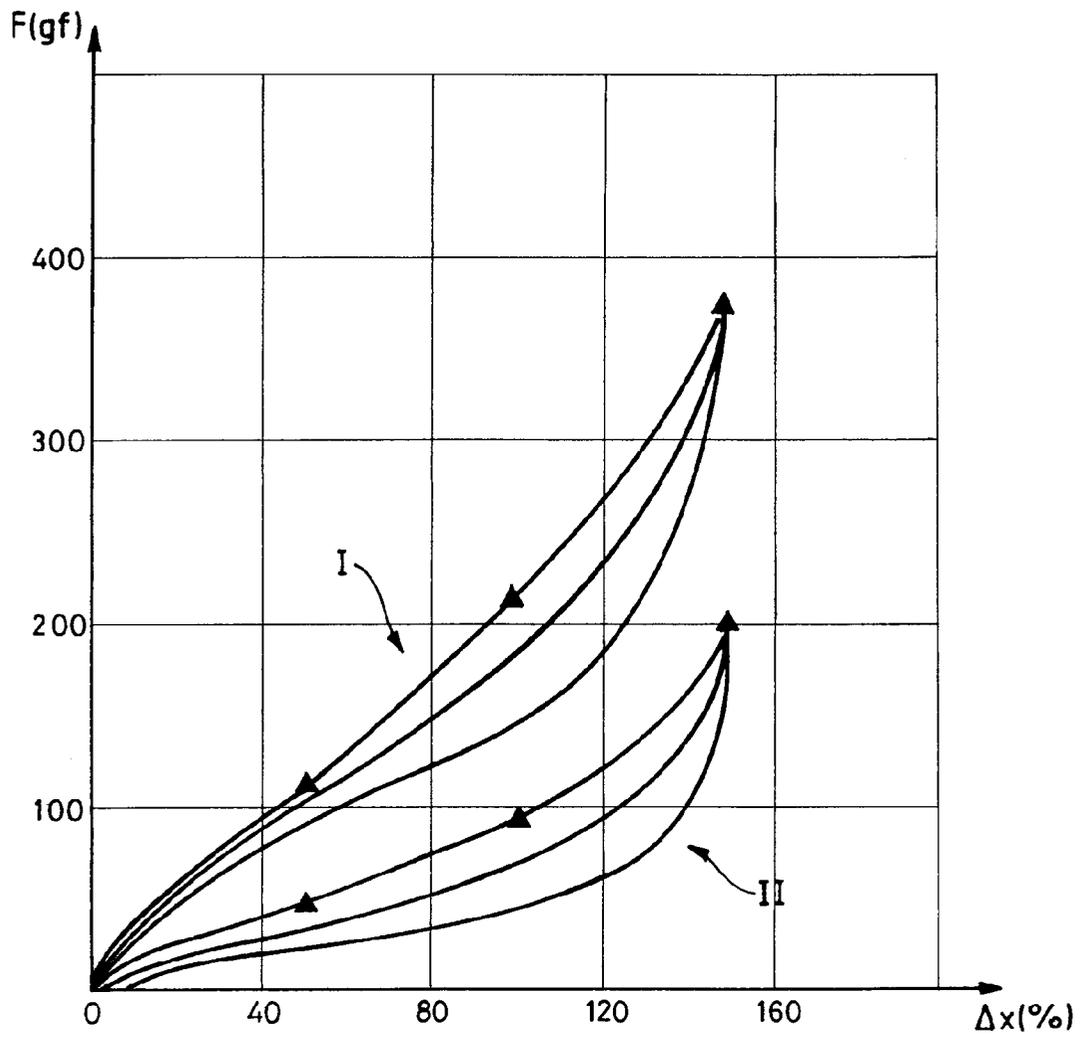
5/ The orthosis of claim 1, whereby the stocking is
30 suitable for exerting compressive pressures with a ration
between the thigh and the ankle less than 125%.

6/ The orthosis of claim 1, whereby the stocking is suitable for exerting compressive pressure with a ratio between the thigh and the ankle not less than 80%.

1/1



FIG_1



FIG_2