



University of Groningen

Insole for reducing peak pressures under a foot

Reints, Roy; Hijmans, Juha Markus; Verkerke, Gijsbertus Jacob; Postema, Klaas

IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

Document Version Publisher's PDF, also known as Version of record

Publication date: 2020

Link to publication in University of Groningen/UMCG research database

Citation for published version (APA):

Reints, R., Hijmans, J. M., Verkerké, G. J., & Postema, K. (2020). Insole for reducing peak pressures under a foot. (Patent No. WO2020055238).

Other than for strictly personal use, it is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license (like Creative Commons).

The publication may also be distributed here under the terms of Article 25fa of the Dutch Copyright Act, indicated by the "Taverne" license. More information can be found on the University of Groningen website: https://www.rug.nl/library/open-access/self-archiving-pure/taverneamendment.

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

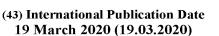
Downloaded from the University of Groningen/UMCG research database (Pure): http://www.rug.nl/research/portal. For technical reasons the number of authors shown on this cover page is limited to 10 maximum.

Download date: 04-06-2022

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization

International Bureau







(10) International Publication Number WO 2020/055238 A1

(51) International Patent Classification:

 A43B 1/00 (2006.01)
 A43B 17/02 (2006.01)

 A43B 13/18 (2006.01)
 A43B 17/14 (2006.01)

(21) International Application Number:

PCT/NL2019/050531

(22) International Filing Date:

15 August 2019 (15.08.2019)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

18193955.4 12 September 2018 (12.09.2018) EP

(71) Applicants: RIJKSUNIVERSITEIT GRONINGEN [NL/NL]; Broerstraat 5, 9712 CP Groningen (NL). ACADEMISCH ZIEKENHUIS GRONINGEN [NL/NL]; Hanzeplein 1, 9713 GZ Groningen (NL).

(72) Inventors: REINTS, Roy; University Medical Center Groningen, Department of Rehabilitation Medicine, Antonius Deusinglaan 1, 9713 AV Groningen (NL). HIJMANS, Juha Markus; University Medical Center Groningen, Department of Rehabilitation Medicine, Antonius Deusinglaan 1, 9713 AV Groningen (NL). VERKERKE, Gijsbertus Jacob; University Medical Center Groningen, Department of Rehabilitation Medicine, Antonius Deusinglaan 1, 9713 AV Groningen (NL). POSTEMA, Klaas; University Medical Center Groningen, Department of Rehabilitation Medicine, Antonius Deusinglaan 1, 9713 AV Groningen (NL).

(74) Agent: WITMANS, H.A.; V.O., P.O. Box 87930, 2508 DH Den Haag (NL).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN,

(54) Title: INSOLE FOR REDUCING PEAK PRESSURES UNDER A FOOT.

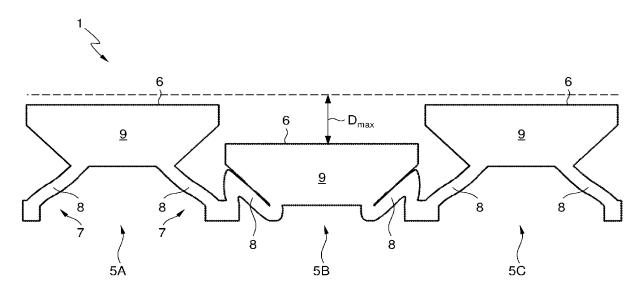


FIG. 4

(57) **Abstract:** The invention provides an insole (1) comprising a plurality of supporting elements (5A, 5B, 5C) distributed over the insole surface for resiliently supporting a foot. Each supporting element comprises a main supporting portion (9) having a narrowing outer shape, and a widening circumferential buckling wall (7) designed to have a buckling behaviour such that: (i) the buckling wall collapses in reaction to a condition in which an external compressive force exceeds a first force threshold (F1); and (ii) if thus being collapsed, the buckling wall resiliently expands in reaction to a condition in which said external compressive force falls below a second force threshold (F2), which is lower than the first force threshold. In use the insole provides a highly effective dynamically self-adjusting pressure distribution reducing peak pressures under a foot, dynamically when the patient walks. In addition, the insole is compact, non complex, easy to produce, durable and reliable.

HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

Insole for reducing peak pressures under a foot

The invention relates to an insole for reducing peak pressures under a foot.

In the present context it is noted that the term "insole", as used throughout the present document, may refer to a removable or fixed inner sole of a boot or shoe.

5

10

15

20

25

Reducing peak pressures under feet of various people may be desirable for various reasons. It is, for example, particularly desirable for people with diabetes. The reason is that high peak pressures under the feet of people with diabetes can result in diabetic foot ulcers. These ulcers may eventually lead to (partial) amputation of the affected lower limb. Keeping peak pressures below 200 KPa prevents ulcerations.

Custom made insoles are commonly used. In the best situation these are based on a one time pressure measurement. Production processes like 3D printing and CAD have helped with decreasing production costs of these insoles. However, over time pressure spots change due to changes in the foot structure and the insole does not adapt to these changes.

US2017348181A1 discloses an insole, which actually does adapt to changes in the foot structure over time. In fact, the insole known from US2017348181A1 even effectively adapts to changes in pressure spots, dynamically when the patient walks. This known insole is capable of changing along when pressure spots change during walking. However, this known insole is very complex, as well as very expensive. The reason is that this known insole has a layer of many modules, wherein each module has many co-operating parts and aspects, such as a deformable cushion with a cavity, a valve, a tank, a pressure sensor, and a feedback loop.

It is further noted that WO 2018/115874 A1 discloses an insole according to the pre-characterizing portion of appended independent claim 1 of the present disclosure.

2

It is an object of the present invention to provide at least an alternative insole for reducing peak pressures under a foot, wherein the insole is effective to adapt to changes in pressure spots, dynamically when the patient walks, and wherein the insole is less complex and less expensive than the insole known from the above-mentioned US2017348181A1.

5

10

15

20

25

For that purpose, the invention provides an insole according to the appended independent claim 1. Preferable embodiments of the invention are provided by the appended dependent claims 2-7.

Hence, the invention provides an insole for reducing peak pressures under a foot, wherein the insole has an insole surface in accordance with a width direction and a length direction of the insole, and wherein the insole comprises a plurality of resilient supporting elements, which are distributed over the insole surface for resiliently supporting a foot in a supporting direction, which is transverse to the insole surface, and wherein, for each supporting element of said plurality of supporting elements, the supporting element has an undeformed condition, from which the supporting element is resiliently deformable under influence of an external compressive force, which is exerted on the supporting element in the supporting direction, the supporting element having a supporting surface for receiving said external compressive force, and wherein the supporting element returns into said undeformed condition in reaction to a condition in which said external compressive force vanishes, and wherein the supporting element comprises a resiliently collapsable buckling part designed to have a buckling behaviour such that:

- the buckling part resiliently collapses in the supporting direction in reaction to a condition in which said external compressive force exceeds a first force threshold, and,
- if thus being collapsed, the buckling part resiliently expands in the supporting direction in reaction to a condition in which said external

WO 2020/055238

5

10

15

20

25

3

PCT/NL2019/050531

compressive force falls below a second force threshold, which is lower than the first force threshold,

wherein, as seen in said undeformed condition of the supporting element, the buckling part of the supporting element is formed by an elastically deformable circumferential buckling wall, which is extending circumferentially around a central axis of the supporting element, said central axis of the supporting element being parallel to the supporting direction, and

characterized in that,

as seen in said undeformed condition of the supporting element, and as seen in at least one cross-sectional plane containing said central axis of the supporting element:

- the supporting element further comprises a main supporting portion, wherein said supporting surface is an outer surface of the main supporting portion,
- the main supporting portion in at least a sub-range along said central axis has a narrowing outer shape, such as for example a frustoconically narrowing outermost shape, as seen in a direction away from said supporting surface,
- the circumferential buckling wall is on a side of the main supporting portion facing away from said supporting surface, and
- the circumferential buckling wall in at least a sub-range along said central axis is widening, such as for example conically widening, as seen in a direction away from said supporting surface.

It is noted that the terms "resilient" and "resiliently", as used throughout the present document in relation to the above-mentioned supporting element, generally refer to the ability of the supporting element to automatically spring back into shape after being compressed in the above-mentioned supporting direction. Said springing back is occurring towards

4

the above-mentioned undeformed condition of the supporting element and is based on spring force provided by the supporting element itself.

It is further noted that the term "buckling", as used throughout the present document in relation to the above-mentioned supporting element, more particularly as used in relation to the above-mentioned resiliently collapsable "buckling" part having the above-mentioned "buckling" behaviour, is to be understood to mean: angularly bending as a result of a locally abruptly lower bending stiffness of the supporting element.

5

10

15

20

25

30

The foot of the user will exert pressure on the insole, the pressure being distributed over the total number of supporting elements that are present. The resulting pressure distributed over the surface of an individual supporting element results in a compressive force proportional to the pressure and surface area of the supporting element. This compressive force causes the supporting element to buckle.

As will be readily appreciated from the more detailed example of the drawing figures discussed further below, the resiliently collapsable buckling part with its buckling behaviour can be noncomplex, easy to produce, durable and reliable.

The key features of the insole according to the invention are:

- the plurality of the above-mentioned supporting elements distributed over the insole surface, in combination with
- the fact that each supporting element has the above-mentioned resiliently collapsable buckling part having the above-mentioned collapsing and expanding buckling behaviours in dependence of how the external compressive force behaves relative to the above-mentioned first and second force thresholds, and in combination with
- the above-mentioned narrowing outer shape of the main supporting portion and the above-mentioned widening circumferential buckling wall.

5

Thanks to these key features local peak pressures are effectively prevented, since one or more of the collapsable buckling parts of one or more of the supporting elements will immediately collapse in case the external compressive force exceeds the first force threshold. Thanks to the collapsing of the buckling part(s) concerned high pressures are automatically prevented at the supporting element(s) concerned. At the same time a larger number of neighbouring supporting elements in unison will take over the load from the supporting element(s) concerned. Hence, the insole according to the invention automatically and dynamically prevents local peak pressures by redistributing the pressures over a larger number of neighbouring supporting elements. In other words, the insole according to the invention provides a highly effective dynamically self-adjusting pressure distribution for reducing peak pressures under a foot. Thanks to the abovementioned narrowing outer shape of the main supporting portion and the above-mentioned widening circumferential buckling wall, the major feature of the invention, i.e. the supporting element as a whole, is realized in a compact, noncomplex, nonexpensive and reliable manner.

5

10

15

20

25

30

In a preferable embodiment of the invention, said plurality of resilient supporting elements is an integrally manufactured one-piece structure. Such an integrally manufactured one-piece structure further contributes to the noncomplex and/or nonexpensive character of the insole. The one-piece structure may for example be made by a 3D printer. However, many various other manufacturing techniques are available as well, for example various 3D layerwise manufacturing technologies, injection moulding technologies, etc.

In further preferable embodiments of the invention,

- an external pressure exerted on the supporting surface of the supporting element and a first pressure threshold for said external pressure are defined as to proportionally correspond, in terms of uniform pressure distribution over the supporting surface, to the external compressive force

6

exerted on the supporting element and the first force threshold, respectively, and

5

10

15

20

25

- said first pressure threshold is higher than 100 KPa and lower than 300 KPa; more preferably higher than 140 KPa and lower than 250 KPa; and yet more preferably higher than 180 KPa and lower than 200 KPa. Depending on the circumstances, these values of the first pressure threshold may reduce peak pressures under a foot to effective levels for preventing various foot problems, such as for example diabetic foot ulcers.

In further preferable embodiments of the invention, the second force threshold is higher than 10% of the first force threshold and lower than 95% of the first force threshold; more preferably higher than 20% of the first force threshold and lower than 85% of the first force threshold; and yet more preferably higher than 30% of the first force threshold and lower than 75% of the first force threshold.

Making designs choices so as to obtain values of the second pressure threshold within the above-mentioned ranges, may, depending on the circumstances, contribute to obtaining a favorably even pressure distribution under a foot as seen dynamically when the patient walks. The closer the second pressure threshold is to the first pressure threshold, the sooner the supporting elements will tend to expand again after being collapsed.

In another preferable embodiment of the invention the circumferential buckling wall in collapsed condition of the buckling part is received against the narrowing outer shape of the main supporting portion.

This further contributes to obtaining a compactly collapsing buckling part of the supporting element.

In another preferable embodiment of the invention the main supporting portion is a solid portion of the supporting element in the sense of not being hollow and not containing spaces or gaps.

7

Such a solid portion further contributes to a favourable deformation behaviour of the supporting element, and it also contributes to a stable supporting behaviour as provided by the supporting element.

In another preferable embodiment of the invention:

5

10

15

20

25

30

- transverse outermost boundary contours of the supporting element are defined as outermost boundary contours of the supporting element, respectively, as seen at least in said undeformed condition of the supporting element, and as seen in cross-sectional planes, which at different positions along said central axis, respectively, are transverse to said central axis, and

- wherein at least one of said outermost boundary contours, and preferably all of said outermost boundary contours, of the supporting element has/have an hexagonal shape.

The hexagonal shape provides the following advantages for providing predictable and reproducible buckling behavior of the supporting elements. The hexagonal shape allows for a maximum of six neighboring elements for each supporting element as opposed to for example a square shape where only a maximum of four neighboring elements may be achieved. In this manner the hexagonal shape advantageously maximizes the amount of neighboring elements that can take over the load from a supporting element, the hexagonal shape thus optimally redistributes the pressure over said neighboring supporting elements.

The hexagonal shape also allows for an even distance between the outermost boundary contours of adjacent supporting surfaces thus providing a more uniform surface for more effectively redistributing the pressure, as opposed to for example a round shape which would leave more space inbetween adjacent supporting elements.

Furthermore, the hexagonal shape advantageously allows for the largest number of supporting elements distributed over het insole surface, thus maximizing the amount of supporting elements on the insole

8

The above-mentioned aspects and other aspects of the invention will be apparent from and elucidated with reference to the embodiments described hereinafter by way of non-limiting examples only and with reference to the schematic figures in the enclosed drawing.

Fig. 1 shows, in a perspective view, an example of an embodiment of an insole according to the invention, wherein the supporting elements of the insole are in their undeformed conditions.

5

10

15

20

25

30

Fig. 2 separately shows, in a perspective view, one of the plurality of resilient supporting elements of the insole of Fig. 1, wherein the shown supporting element is in its undeformed condition.

Fig. 3A shows the supporting element of Fig. 2 in its undeformed condition, however this time in a cross-sectional plane which contains the central axis of the supporting element.

Fig. 3B shows the situation of Fig. 3A again, however this time in a deformation condition of the supporting element in which an external compressive force is exerted on the supporting element in the supporting direction, wherein the external compressive force is lower than the abovementioned first force threshold, so that the buckling part of the supporting element has not yet collapsed in the supporting direction.

Fig. 3C shows the situation of Fig. 3B again, however this time in a condition in which said external compressive force exerted on the supporting element has exceeded said first force threshold, so that the buckling part of the supporting element has collapsed in the supporting direction.

Fig. 4 separately shows three mutually adjacent ones of the plurality of resilient supporting elements of the insole of Fig. 1, in a cross-sectional plane which contains the central axes of the three supporting elements, wherein the leftmost and rightmost of the three supporting elements are in the deformation condition of Fig. 3B, while the middle one of the three supporting elements is in the deformation condition of Fig. 3C.

9

Fig. 5 shows a qualitative force/displacement graph, which is typical for a supporting element, such as the specific supporting element of Fig. 2, wherein the graph depicts, for each considered standstill displacement of the supporting element, the resilient reaction force provided by the supporting element when balanced by an oppositely directed equal external compressive force exerted on the supporting element at each considered standstill displacement, respectively.

5

10

15

Fig. 6 shows a full-line graph and a broken-line graph, both as a function of time, wherein the full-line graph is an example of a qualitative force/time graph during a gait cycle performed by a person, the full-line graph qualitatively indicating an imposed external compressive force exerted on a supporting element, such as the specific supporting element of Fig. 2, as a function of time, and wherein the broken-line graph qualitatively indicates the correspondingly resulting displacement of the supporting surface of the supporting element as a function of time during said gait cycle.

The reference signs used in Figs. 1-6 are referring to the abovementioned parts and aspects of the invention, as well as to related parts and aspects, in the following manner.

20	1 insole
	2 width direction
	3 length direction
	4 supporting direction
	5, 5A, 5B, 5C supporting element
25	6 supporting surface
	7 collapsable buckling part
	$8\;\; circumferential\; buckling\; wall$
	9 main supporting portion
	10 central axis
30	F_1 first force threshold

10

 F_2 ------ second force threshold D_{max} ----- maximum displacement of the supporting surface (as seen relative to the undeformed condition of

the supporting element).

5

10

15

20

25

Based on the above introductory description, including the brief description of the drawing figures, and based on the above-explained reference signs used in the drawing, the shown examples of Figs. 1-6 are for the greatest part readily self-explanatory. The following extra explanations are given.

The insole 1 illustrated by Figs. 1-6 is an insole according to each of the appended independent claims 1-7.

As seen in Fig. 1, the insole 1 has a large plurality of mutually identical supporting elements, generally indicated by the reference numeral 5. Three mutually adjacent ones of these identical supporting elements 5 have more specifically been indicated by the reference numerals 5A, 5B, 5C, respectively. These are the three supporting elements 5A, 5B, 5C which are also shown in the cross-sectional plane of Fig. 4. In Fig. 1 it is further seen that the insole 1 of Fig. 1 further has a number of supporting elements, which are different from said mutually identical supporting elements 5. These different supporting elements are located along the outer circumferential boundary edge of the insole 1. In fact these different supporting elements are truncated versions of the supporting elements 5.

In the shown example all supporting elements of the insole 1 are interconnected with one another via the circumferential buckling walls 8 of their collapsable buckling parts 7 in a manner as shown in Fig. 4, thereby forming the insole 1 as an integrally manufactured one-piece structure. In fact, the integrally manufactured one-piece insole 1 has been manufactured by means of a 3D-printer.

11

Figs. 2-4 show the above-mentioned narrowing outer shape of the main supporting portion 9 of the supporting element 5, as seen in a direction away from the supporting surface 6. More specifically it is seen that, in the shown example, said narrowing outer shape is a frusto-conically narrowing outermost shape.

Figs. 2-4 further show that the circumferential buckling wall 8 is widening in a manner as mentioned above. More specifically it is seen that, in the shown example, the circumferential buckling wall 8 is conically widening, as seen in a direction away from the supporting surface 6.

5

10

15

20

25

30

As seen in Figs. 3-4, the conically widening circumferential buckling wall 8, at least in the undeformed condition of the supporting element 5, is defining a recess of the supporting element 5. The main supporting portion 9, on the other hand, is a solid portion of the supporting element 5 in the shown example.

Furthermore, Figs. 1-2 show the above-mentioned hexagonal shapes of the above-mentioned outermost boundary contours of the supporting element 5. More specifically, in the shown example said hexagonal shapes of the outermost boundary contours are occurring along the entire extension range of the supporting element 5 along the central axis 10.

Figs. 3A-3C are illustrating the deformation behaviour of the supporting element 5, including the buckling behaviour of the collapsable buckling part 7, under influence of external compressive forces exerted on the supporting surface 6 of the supporting element in the supporting direction. The undeformed condition of the supporting element 5 as shown in Fig. 3A corresponds to a situation in which the external compressive force is absent.

The condition of the supporting element 5 as shown in Fig. 3B corresponds to a situation in which the external compressive force is present, but does not exceed the first force threshold F₁, so that the buckling

12

part 7 of the supporting element has only been deformed slightly, but has not yet collapsed. Accordingly, in Fig. 3B it is seen that the supporting surface 6 has been only slightly displaced relative to its position (indicated by a broken line) that would correspond to the undeformed condition of the supporting element 5.

5

10

15

20

25

30

The condition of the supporting element 5 as shown in Fig. 3C corresponds to a situation in which the external compressive force is present, and has exceeded the first force threshold F_1 , so that the buckling part 7 of the supporting element has fully collapsed. That is, in Fig. 3B it is seen that the supporting surface 6 has been displaced over the maximum displacement D_{max} relative to its position (indicated by a broken line) that would correspond to the undeformed condition of the supporting element 5.

If, starting-off from the collapsed situation shown in Fig. 3C, the external compressive force would fall below the second force threshold F_2 (which is lower than the first force threshold F_1), the buckling part 7 would resiliently expand in such manner that the supporting element 5 would attain a deformation condition similar to that shown in Fig. 3B, or, if the external compressive force would fully vanish, the undeformed condition of Fig. 3A.

Reference is now made to Fig. 5 in order to further explain the deformation behaviour of the supporting element 5, including the buckling behaviour of the collapsable buckling part 7, under influence of external compressive forces exerted on the supporting surface 6 of the supporting element in the supporting direction.

As already mentioned in the introduction, the resilient supporting element 5 has the ability to automatically spring back into shape after being compressed in the supporting direction. Said springing back is based on spring force provided by the supporting element itself. In that sense, the supporting element 5 is for example comparable with a compression spring. A compression spring has a "spring constant", which defines a linear

13

relationship between external compressive force and displacement. The resilient supporting element of the insole of the present invention, on the other hand, has a totally different relationship between external compressive force and displacement. This is illustrated by Fig. 5, wherein the horizontal axis depicts the displacement of the supporting surface 6 of the supporting element 5, between 0 millimeter and D_{max} , and wherein the vertical axis depicts the involved external compressive force, between 0 Newton and F_1 .

5

10

15

20

25

30

Fig. 5 shows that at the start of deforming the supporting element 5, there is a more or less linear relationship between external compressive force and displacement. Next, when the external compressive force reaches the first force threshold F_1 , the collapsable buckling part 7 starts to collapse, meaning that the resilient reaction force of the supporting element 5 drastically decreases in combination with a drastically increased displacement, eventually upto the maximum displacement D_{max} . To maintain the maximum displacement D_{max} , it suffices that the external compressive force is higher than or equal to the second force threshold F_2 .

It is noted that, in the shown example, the first and second force thresholds F_1 and F_2 are dependent on various design choices of the supporting element 5. For example, in the shown example it has appeared that these first and second force thresholds F_1 and F_2 are highly influenceable by the wall thickness of the circumferential buckling wall 8, as well as by the angle between the circumferential buckling wall 8 and the central axis 10 as important design parameters.

Reference is now made to Fig. 6 in combination with Fig. 4. In Fig. 6 the full-line graph could for example indicate an imposed external compressive force exerted on the supporting element 5B of Fig. 4 during a gait cycle performed by a person, wherein the broken-line graph of Fig. 6 indicates the correspondingly resulting displacement of the supporting surface 6 during said gait cycle. From Fig. 6 it is seen that the supporting

14

element 5B of Fig. 4 is in fully collapsed condition during a major part of the gait cycle. Fig. 4 illustrates that, when the supporting element 5B is collapsed, the neighbouring supporting elements, such as the elements 5A and 5C of Fig. 4, in unison will take over the load from the supporting element 5B. Accordingly, Figs. 4 and 6 make clear that local peak pressures under a foot are effectively prevented thanks to the insole 1, since one or more of the collapsable buckling parts of one or more of the supporting elements of the insole 1 will immediately collapse in case the external compressive force exceeds the first force threshold. Thanks to the collapsing of the buckling part(s) concerned high pressures are automatically prevented at the supporting element(s) concerned. At the same time a larger number of neighbouring supporting elements in unison will take over the load from the supporting element(s) concerned. Hence, the insole according to the invention automatically and dynamically prevents local peak pressures by redistributing the pressures over a larger number of neighbouring supporting elements. In other words, the insole according to the invention provides a highly effective dynamically self-adjusting pressure distribution for reducing peak pressures under a foot.

5

10

15

20

25

30

Prototypes of the invention were manufactured by Fused Deposition Modelling 3D printers using thermoplastic polyurethane filament. Each supporting element 5 was manufactured with a height of 9 mm, a supporting surface 6 area of $1.46~\rm cm2$, a $D_{\rm max}$ of $3.5~\rm mm$. Again, specific pressures over the supporting surface 6 will result in proportional values for the force thresholds. Different values for the main design parameters, said design parameters being wall thickness of the circumferential buckling wall 8, the angle between the circumferential buckling wall 8 and the central axis 10, were manufactured and these resulted in the following example first force thresholds (F_1) and example second force thresholds (F_2) during quasi-static measurements that provided good functionality:

15

Wall Thickness	Angle	\mathbf{F}_1	\mathbf{F}_2
0.90 mm	40°	14.9 N / 102 kPa	10.8 N / 74 kPa
1.05 mm	40°	19.3 N / 132 kPa	13.7 N / 94 kPa
1.20 mm	40°	28.9 N / 198 kPa	19.6 N / 134 kPa
0.90 mm	45°	11.4 N / 78 kPa	8.1 N / 55 kPa
1.05 mm	45°	15.4 N / 105 kPa	10.5 N / 72 kPa
1.20 mm	45°	20.9 N / 143 kPa	15.0 N / 103 kPa

The values shown for F_1 and F_2 are the compressive force measured on the supporting surface, and the corresponding local pressure on the supporting surface at buckling (F_1) and springing back (F_2). It is noted that these example values were identified by the inventors under laboratory conditions as providing good functionality, but other values for the wall thickness of the circumferential buckling wall 8, the angle between the circumferential buckling wall 8 and the central axis 10 may be identified with further development that also provide equal or better functionality.

5

10

15

20

It is noted that in Fig. 1 the width direction 2 and the length direction 3 of the insole are both depicted as straight linear directions. Generally, however, both the width direction 2 and the length direction 3 may also be curved directions, so that also the insole surface of the insole may generally be a two-dimensionally curved surface. In fact the insole 1 of Fig. 1 is a deformable structure in both said directions.

While the invention has been described and illustrated in detail in the foregoing description and in the drawing figures, such description and illustration are to be considered exemplary and/or illustrative and not restrictive; the invention is not limited to the disclosed embodiments.

For example, in the shown example, the outermost boundary contours of the supporting element 5 have hexagonal shapes. Instead, many various other shapes of such outermost boundary contours are also possible

16

according to the invention, such as circular, oval, or otherwise rounded shapes, or triangular, square, or otherwise piecewise linear shapes, etc.

5

10

15

20

25

As a further example it is mentioned that one insole according to the invention may comprise different kinds of the supporting elements, having different shapes, collapsing properties, etc., instead of all the same supporting elements. For example, the different kinds of supporting elements may be located in different zones along the support surface of the insole, respectively. In fact, an insole according to the invention may be designed both as a custom design and as an off-the-shelf design.

It is further noted that an insole according to the invention may not only be beneficial for people with diabetes. It may also be beneficially applied to many various other boots or shoes, such as for example to many various sportsshoes.

Other variations to the disclosed embodiments can be understood and effected by those skilled in the art in practicing the claimed invention, from a study of the drawings, the disclosure, and the appended claims. In the claims, the word "comprising" does not exclude other elements or steps, and the indefinite article "a" or "an" does not exclude a plurality. A single part may fulfill the functions of several items recited in the claims. For the purpose of clarity and a concise description, features are disclosed herein as part of the same or separate embodiments, however, it will be appreciated that the scope of the invention may include embodiments having combinations of all or some of the features disclosed. The mere fact that certain measures are recited in mutually different dependent claims does not indicate that a combination of these measures can not be used to advantage. Any reference signs in the claims should not be construed as limiting the scope.

17

Claims

1. An insole for reducing peak pressures under a foot, wherein the insole (1) has an insole surface in accordance with a width direction (2) and a length direction (3) of the insole, and wherein the insole comprises a plurality of resilient supporting elements (5, 5A, 5B, 5C), which are distributed over the insole surface for resiliently supporting a foot in a supporting direction (4), which is transverse to the insole surface, and wherein, for each supporting element of said plurality of supporting elements, the supporting element has an undeformed condition, from which the supporting element is resiliently deformable under influence of an external compressive force, which is exerted on the supporting element in the supporting direction, the supporting element having a supporting surface (6) for receiving said external compressive force, and wherein the supporting element (5) returns into said undeformed condition in reaction to a condition in which said external compressive force vanishes, and wherein the supporting element (5) comprises a resiliently collapsable buckling part (7) designed to have a buckling behaviour such that:

5

10

15

20

25

- the buckling part (7) resiliently collapses in the supporting direction in reaction to a condition in which said external compressive force exceeds a first force threshold (F1), and,

- if thus being collapsed, the buckling part (7) resiliently expands in the supporting direction in reaction to a condition in which said external compressive force falls below a second force threshold (F2), which is lower than the first force threshold (F1),

wherein, as seen in said undeformed condition of the supporting element (5), the buckling part (7) of the supporting element is formed by an elastically deformable circumferential buckling wall (8), which is extending circumferentially around a central axis (10) of the supporting element, said

18

central axis of the supporting element being parallel to the supporting direction (4), and

characterized in that,

5

15

as seen in said undeformed condition of the supporting element (5), and as seen in at least one cross-sectional plane containing said central axis (10) of the supporting element:

- the supporting element further comprises a main supporting portion (9), wherein said supporting surface (6) is an outer surface of the main supporting portion,
- the main supporting portion (9) in at least a sub-range along said central axis (10) has a narrowing outer shape, such as for example a frusto-conically narrowing outermost shape, as seen in a direction away from said supporting surface (6),
 - the circumferential buckling wall (8) is on a side of the main supporting portion (9) facing away from said supporting surface (6), and
 - the circumferential buckling wall (8) in at least a sub-range along said central axis (10) is widening, such as for example conically widening, as seen in a direction away from said supporting surface (6).
- 20 2. An insole according to claim 1, wherein said plurality of resilient supporting elements (5) is an integrally manufactured one-piece structure.
 - 3. An insole according to claim 1 or 2, wherein:
- an external pressure exerted on the supporting surface (6) of the supporting element (2) and a first pressure threshold for said external pressure are defined as to proportionally correspond, in terms of uniform pressure distribution over the supporting surface, to the external compressive force exerted on the supporting element and the first force threshold (F1), respectively, and

19

- said first pressure threshold is higher than 100 KPa and lower than 300 KPa; preferably higher than 140 KPa and lower than 250 KPa; and more preferably higher than 180 KPa and lower than 200 KPa.

- 4. An insole according to any one of the preceding claims, wherein the second force threshold (F2) is higher than 10% of the first force threshold (F1) and lower than 95% of the first force threshold (F1); preferably higher than 20% of the first force threshold (F1) and lower than 85% of the first force threshold (F1); and more preferably higher than 30% of the first force threshold (F1) and lower than 75% of the first force threshold (F1).
 - 5. An insole according to any one of the preceding claims, wherein the circumferential buckling wall (8) in collapsed condition of the buckling part (7) is received against the narrowing outer shape of the main supporting portion (9).

15

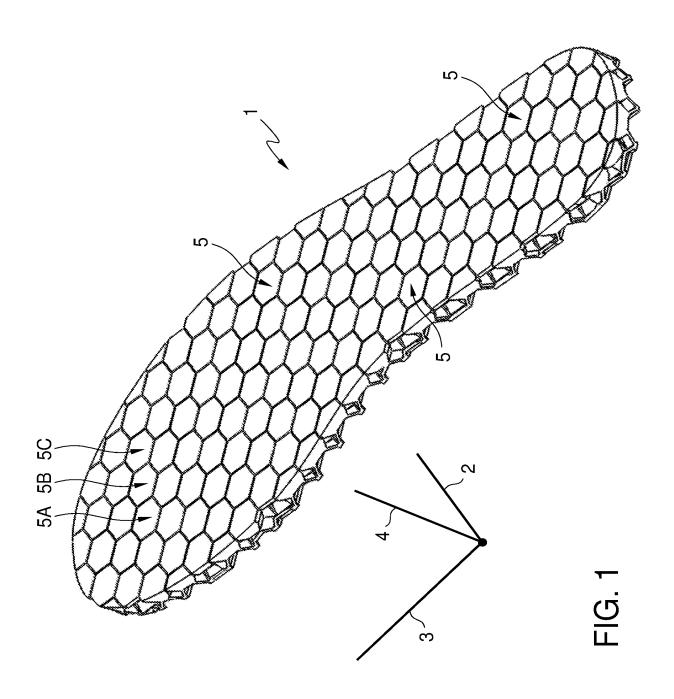
20

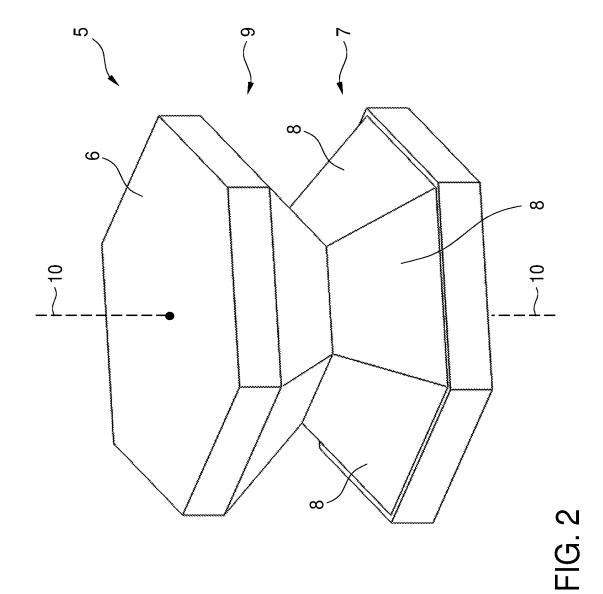
25

- 6. An insole according to any one of the preceding claims, wherein the main supporting portion (9) is a solid portion of the supporting element (5) in the sense of not being hollow and not containing spaces or gaps.
- 7. An insole according to any one of the preceding claims, wherein:
- transverse outermost boundary contours of the supporting element (5) are defined as outermost boundary contours of the supporting element, respectively, as seen at least in said undeformed condition of the supporting element, and as seen in cross-sectional planes, which at different positions along said central axis (10), respectively, are transverse to said central axis, and

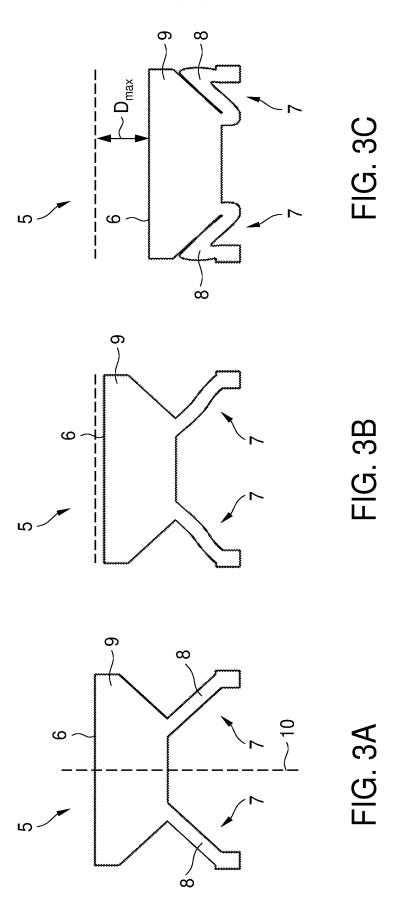
20

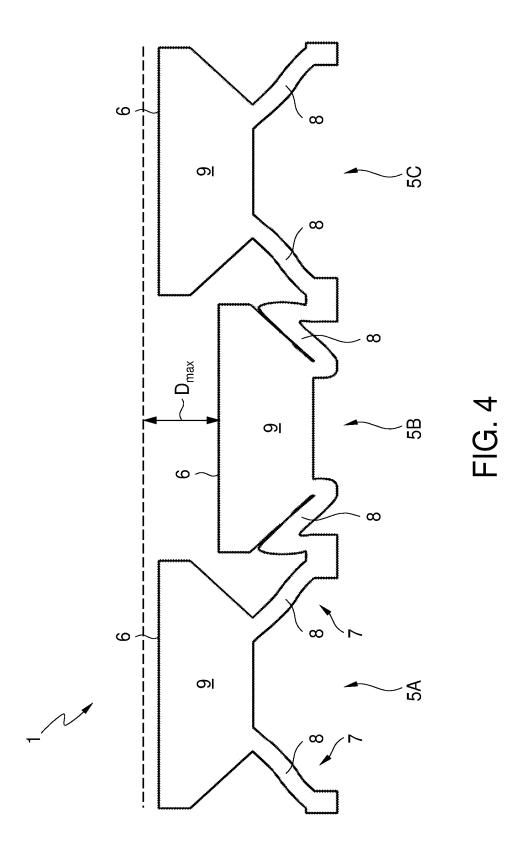
- wherein at least one of said outermost boundary contours, and preferably all of said outermost boundary contours, of the supporting element (5) has/have an hexagonal shape.

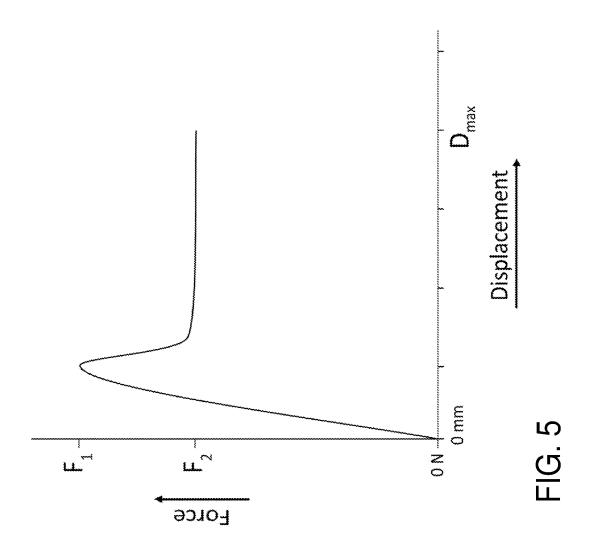


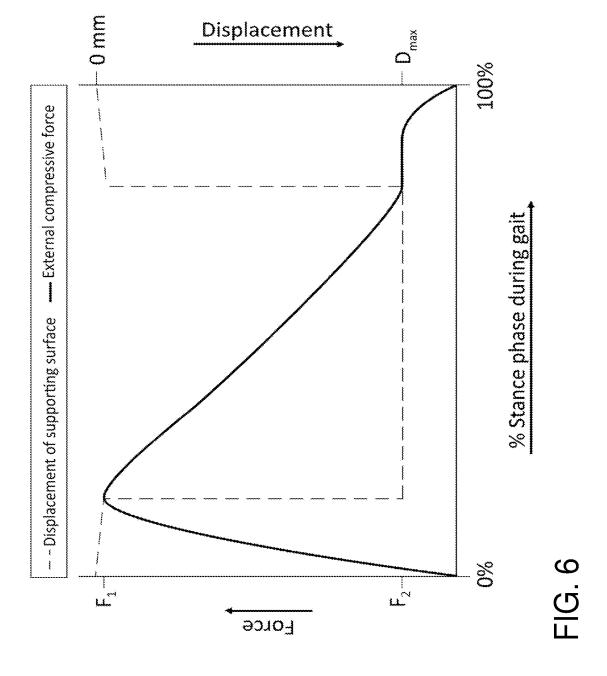












INTERNATIONAL SEARCH REPORT

International application No PCT/NL2019/050531

A. CLASSIFICATION OF SUBJECT MATTER
INV. A43B1/00 A43B13/18 A43B17/02 A43B17/14
ADD.

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)

A43B

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)

EPO-Internal, WPI Data

C. DOCUM	ENTS CONSIDERED TO BE RELEVANT	
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	KR 101 869 660 B1 (JEONG HAE KEUNG [KR]) 20 June 2018 (2018-06-20) paragraph [0050] - paragraph [0061] figures 3A, 3B, 7A, 7B paragraph [0075] - paragraph [0085] paragraph [0012]	1-7
Α	W0 2018/115874 A1 (STAFFORDSHIRE UNIV [GB]) 28 June 2018 (2018-06-28) page 1, line 22 - line 25 page 3, line 11 - line 28 page 17, line 28 - line 31 page 9, line 25 - page 17, line 3 figures 1-4	1-7

X Further documents are listed in the continuation of Box C.	X 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	Date of mailing of the international search report		
4 October 2019	11/10/2019		
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Ariza De Miguel, Jon		

6

INTERNATIONAL SEARCH REPORT

International application No
PCT/NL2019/050531

Category* Cit	tation of document, with indication, where appropriate, of the relevant passages	
	tation of document, with indication, where appropriate, of the relevant passages	I
		Relevant to claim No.
A	WO 2017/196899 A1 (VICIS INC [US]) 16 November 2017 (2017-11-16) paragraph [0078] paragraph [0082] - paragraph [0084] figures 2-4	1-7
A	figures 2-4 US 2017/231322 A1 (GHEORGHIAN PETRE [US] ET AL) 17 August 2017 (2017-08-17) paragraph [0020] figures 2A-2E	

6

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/NL2019/050531

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
KR 101869660	B1	20-06-2018	CN 109936988 A DE 112018000079 T5 KR 101869660 B1 US 2019133252 A1 WO 2019078618 A2	25-06-2019 01-08-2019 20-06-2018 09-05-2019 25-04-2019
WO 2018115874	A1	28-06-2018	EP 3558046 A1 WO 2018115874 A1	30-10-2019 28-06-2018
WO 2017196899	A1	16-11-2017	US 2019069631 A1 WO 2017196899 A1	07-03-2019 16-11-2017
US 2017231322	A1	17-08-2017	NONE	