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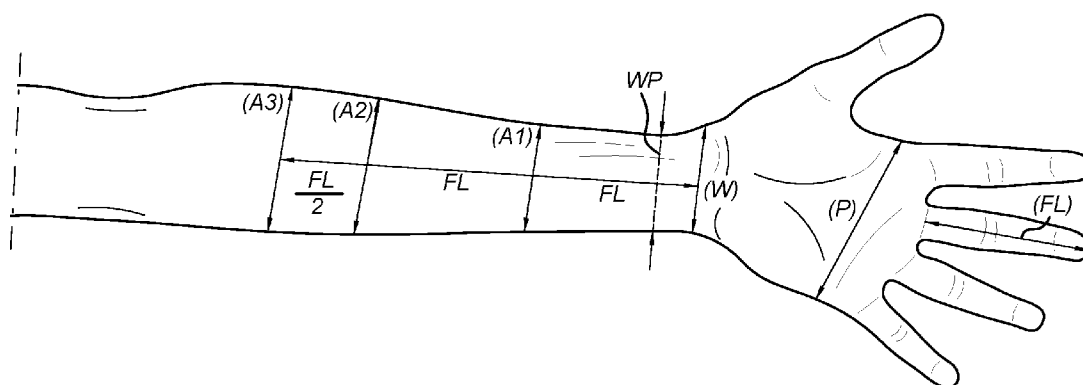
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(54) Title: METHOD AND SYSTEM OF DESIGNING A CUSTOMISED SPLINT FOR A BODY PART

Fig. 1



(57) **Abstract:** A method and system for designing a customised splint (1) for a body part from a sheet of thermoplastic material (6). A 2 dimensional (2-D) image of the body part is obtained, and 3 dimensional (3-D) geometric parameters of the customized splint (1) are extracted, and then translated to a customized shape of the sheet of the thermoplastic material (6). The extraction of the 3-D geometric parameters comprises first extracting a smallest body part width (WP) along a length direction of the imaged body part as a first input parameter, dividing the image into a distal image part and a proximal image part along the length direction using the first input parameter, extracting further input parameters (FL, P, W, A1, A2, A3) from the distal and proximal image parts and using the further input parameters (FL, P, W, A1, A2, A3) and a predetermined model of the body part to obtain the 3-D geometric parameters.



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Method and system of designing a customised splint for a body part**Field of the invention**

5 The present invention relates to a method of designing a customised splint for a body part from a sheet of thermoplastic material. In a further aspect, the present invention relates to a system for designing a customised splint for a body part from a sheet of thermoplastic material.

Background art

10 International patent publication WO201 6/1 4231 9 discloses a method for producing a brace for fixing a position of a broken bone in a first limb, based on an image made using three dimensional scans of the residual limb that corresponds to the first limb. This document further discloses that it is alternatively possible to use a two dimensional (or even a one dimensional) image of the residual limb, without indicating how the image is transferred into a proper brace for the first
15 limb.

American patent publication US2007/001 6323 discloses details on a splint and a method of making such a splint, wherein a 3D scanned image of a body part is used for assisting in making a splint.

American patent publication US201 3/31 7789 discloses a conformable hand brace that
20 includes a support surface for supporting a palm portion of a patient's hand and an adjustable mechanism that allows the cross section of the brace to be adjusted. This system allows the conformable hand brace to be designed automatically by a computer, based upon anatomical measurements using optical photographs.

American patent publication US201 4/142486 discloses a bikini brace that provides the
25 required support or movement resistance at predetermined locations rather than around an entire limb.

International patent publication WO20 15/032006 discloses an orthopaedic support device having a shell supporting a body portion and one or more stimulators provided on the shell for signalling a wearer of the orthopaedic support device to perform a muscular activity.

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Summary of the invention

Traditional methods of casting for healing of fractures in a human or animal body, such as plaster casts made of gypsum or plaster of Paris, have several problems owing to their increased weight or difficulty in performing a frequent washing to it. Thermoplastic materials have emerged
35 as a substitution to the existing materials used for casting. There are several pre-fabricated thermoplastic splints currently available for different conditions and in few different sizes. The problem associated with a pre-fabricated thermoplastic splint is that it needs a recurring process of

trimming, doffing and donning to make it as a customised splint for a specific body part and for a specific fracture. This the process may cause unnecessary discomfort and possibly even pain for a patient and requires a lot of time. The present invention seeks to provide a more efficient method and system for making a customised splint for an individual patient from a sheet of thermoplastic material.

According to the present invention, a method is provided as defined above, wherein the method comprises obtaining a 2-dimensional (2-D) image of the body part, and extracting 3-dimensional (3-D) geometric parameters of the customized splint using 2-D image information from the obtained 2-D image. Extracting of the 3-D geometric parameters comprises extracting a smallest body part width along a length direction of the imaged body part as a first input parameter, dividing the image into a distal image part and a proximal image part along the length direction using the first input parameter, extracting further input parameters from the distal and proximal image parts, using the further input parameters and a predetermined model of the body part to obtain the 3D geometric parameters, and translating the obtained 3D geometric parameters to a customized shape of the sheet of thermoplastic material.

This allows to design a customized splint appropriate for each patient, making it time efficient for both medical staff and more comfortable for patients.

In a further aspect of the present invention, a system is provided as defined above, comprising an image input device (such as a camera) arranged to obtain an image of the body part, and a processing unit connected to the image input device. The processing unit is arranged to execute the method according to any one of embodiments described herein.

Such a system can be provided locally as a compact and stand-alone system, allowing to prepare and even manufacture customised splints for a patient locally in a very efficient and comfortable manner.

Short description of drawings

The present invention will be discussed in more detail below, with reference to the attached drawings, in which

Fig. 1 shows a two dimensional image of a body part, with body part indices used in an exemplary embodiment of the present invention;

Fig. 2 shows a distal image part of a body part as used in an embodiment of the present invention;

Fig. 3 shows a schematic diagram of a system for designing a customized splint for a body part according to an embodiment of the present invention ;

Fig. 4 shows a top view of an example of a sheet of thermoplastic material resulting from applying one of the present invention embodiments; and

Fig. 5 shows an example of a customized splint after application to the body part.

Description of embodiments

Traditional methods of casting, such as plaster casts made of gypsum or plaster of paris, have several problems owing to their increased weight or difficulty in performing a frequent washing to it. This can result in irritations to the skin when in contact with the cast. Alternatives have been devised, such as casts made of fibre glass material. The fibre glass based casts are hard to mould making it difficult to use in splint making. Both the new and old type of existing cast materials have the disadvantage of creating skin problems such as itching which can result in bacterial infection leading to a foul smell and to an unhealthy condition of the patient.

Thermoplastic materials have emerged as a substitution to the materials as conventionally used for casting. Thermoplastic materials are polymer based materials that become mouldable above a specific temperature and returns to a solid state upon cooling. There are several pre-fabricated thermoplastic splints currently available for different conditions, usually provided only in few different sizes. The problem associated with a pre-fabricated thermoplastic splint is that it needs a recurring process of doffing and donning to make it fit for a specific body part and for a specific fracture. Additionally this whole process may be a painful experience to a patient. To make a pre-fabricated thermoplastic splint adjusted to a specific body part, medical staff needs a variety of different kinds of pre-fabricated splints available at their disposal. As the pre-fabricated splints are not fitted for each possible body part, trimming is often necessary which makes it time consuming for both the medical staff and for the patient.

According to the present invention embodiments a solution is provided to design a customized splint appropriate for a body part from a thermoplastic sheet. The method embodiments described herein comprise analysing a two dimensional (2-D) captured image of the body part with a fracture and finding three dimensional data associated with relevant parts of the body part. The 3-D data can then be used for designing and preparing a splint from a thermoplastic material sheet, e.g. also based on the type of the fracture. As the splint has then been designed with proper dimensions and a suitable size, there is no need for any kind of trimming, or other fitting actions like donning, to perform. By capturing just one or two 2-D images, without the need of expensive 3D imaging, the cost and complexity of the process to obtain a customized splint can be reduced. Further, it is not necessary for medical staff to have all different kinds of splints available but only standard thermoplastic sheets are enough. The present invention discloses a method of designing a customised splint for a body part which is quick and user friendly that anyone can use without any specific additional training. In addition, the present invention embodiments are based on using the thermoplastic sheets in which final moulding is performed on the injured limb of the patient. Therefore, calculating the peaks and troughs is not required in the design of the splint which is advantageous compared performing a 3-D scanning.

In the context of this description, a limb is a jointed or prehensile appendage of a human or animal body. In the human body, the upper and lower limbs are commonly known as arms and legs, respectively, with associated wrist and hand, and ankle and foot, respectively. In the creation of human limb, there are specific relations between different parts of the body. As an example, there is specific relations between phalange parts that is approximately constant among all human

beings. This phenomenon is also existing between the 2-D and 3-D sizes of the limb. This allows to define a predetermined model of the body part, which can be used to obtain 3-D geometric parameters from obtained 2-D parameters. As an exemplary application of the present invention embodiments the upper limb (arm) will be discussed as the body part of which an image is taken.

5 Fig. 1 shows a two dimensional image of an exemplary body part, in this case a human arm, with body part indices indicated (which will be explained in further detail below)

One embodiment of the present invention relates to a method of designing a customised splint for a body part from a sheet of thermoplastic material. The method comprises obtaining a 2-D image of the body part (e.g. the image shown in Fig. 1), extracting 3-D geometric parameters of the customized splint using the 2-D image information from the obtained 2-D image and translating the obtained 3D geometric parameters to a customized shape of the sheet of thermoplastic material. The extraction of the 3-D geometric parameters comprises the following. First a smallest body part width along a length direction of the imaged body part is extracted as a first input parameter. For example, in the case of the body part being a human arm as shown in Fig. 1, the first input parameter indicates an approximate position of the wrist on the wrist line WP. Then the image is divided into a distal image part and a proximal image part along the length direction using this first input parameter. For example, in case of a human arm, these two parts might be a palm image and an arm image. Further input parameters are extracted from the distal and proximal image parts. Examples are web points, tip points and palm line position from a palm image, as will be explained in further detail below. Using these further input parameters and a predetermined model of the body part, the 3-D geometric parameters are obtained, after which the obtained 3D geometric parameters are translated to a customized shape of the sheet of thermoplastic material. Thus the 3-D properties of the body part are extracted from one (or more, e.g. two) 2-D image(s) based on the relationships existing between 2D and 3D sizes of different parts of the body. This will allow customizing shape, thickness and exposure of incision according to each patient's unique body parameters and the type of fracture. Manual steps in fitting a splint are prevented using the present invention embodiments. Of course, if required, medical staff is still able to trim the customized splint anyway.

Feature extraction from the 2-D image is used to find details such as the creases, tip and web points, which may form (part of) the further input parameters as used in the present invention embodiments. In order to find the relevant parameters, first the approximate wrist position WP is found on the captured image. In the example shown in Fig. 1, the approximate position of the wrist is found by scanning the boundary of the arm in the 2-D image in a lengthwise direction (i.e. towards the fingers), and finding the smallest width of the surface enclosed by the arm boundary. The 2-D image is then divided in a distal image part and a proximal image part. The distal image part associated with the example image shown in Fig. 1 is shown in Fig. 2. After that an accurate wrist position W is found in the distal (palm) image using a specific algorithm

As indicated in Fig. 2, an image processing technique is used to find the exact wrist point. First the palm centre point P is determined as the point having the overall largest distance from the boundary in the image.

In one specific embodiment of the present invention, and using more generic terms, extracting additional input parameters comprises determining a centre point of the body part (e.g. palm centre point for a hand) using boundary scanning from the distal image part, (i.e. by determining the largest possible distance to a boundary of the hand), and determining a major reference position (e.g. the wrist position W) of the body part relative to the determined centre point. As indicated in Fig. 2, a circle C1 can be determined touching as many points as possible on the hand boundary, and the middle of that circle determined as centre point P. By adding a predetermined radial distance, e.g. using a predetermined scaling factor, a further circle C2 is found on which the exact wrist position (major reference position) is located. In addition, specific further input parameters may be obtained from the distal (palm) image and proximal (arm) image.

The arm has specific body part indices which are indicated in Fig. 1 (and may also be indicated as golden indices). For an arm, these body part indices or golden indices comprise a palm line P, a wrist line W, a first arm point A1, a second arm point A2 and a third arm point A3. From the 2-D image shown in Fig. 1, but more conveniently from the distal image shown in Fig. 2, further parameters may be determined using image processing techniques, such as the finger length FL.

In one specific embodiment of the present invention, one of the further input parameters is a determined finger length FL, and a first distance between the wrist point W and the first arm point A1 and a second distance between the first arm point A1 and the second arm point A2 is equal to the finger length FL, and a third distance between the second arm point A2 and the third arm point A3 is equal to half the finger length FL. In a further embodiment, the body part is a leg (with connected parts ankle and foot), for which corresponding (further) input parameters etc. can be used.

In a further embodiment, extracting further input parameters comprises determining tip and web points of the body part as local maxima and minima distances relative to the centre point using boundary tracing in the distal image part. Tip and web points will be found based on the distance of the boundary of palm image from the major reference position (i.e. wrist middle point), e.g. local maxima and minima of the traced distance correspond to tip and web points, respectively, in the specific example shown, the maxima representing the tips of the fingers and the points between fingers.

In one further embodiment of the present invention, extracting further input parameters comprises image processing of the distal image part for detecting creases (see Fig. 1 and 2 for examples of such creases), and determining further input parameters from the detected creases, e.g. palm line orientation and palm width, wrist line orientation and wrist width in the case of a hand. Palm line extraction may be based on crease detection algorithms using Gaussian gradient of the binary image and using appropriate morphological operations.

Using the embodiments described above, e.g. the finger length (FL) parameter may be determined, which, as shown in Fig. 1, can be used to exactly determine the first, second and third arm point locations from the exact wrist point position.

In an even further embodiment of the present invention, extracting additional input parameters thus comprises image processing of the proximal image part. This might comprise of

determining arm points, possibly using finger length and (exact) wrist position which are determined from the distal image.

Using the present invention embodiments, it is possible to directly or indirectly manufacture a customized splint from a sheet of thermoplastic material. In a specific embodiment of the present invention, the method further comprises manufacturing the customized splint using the 3D geometric parameters as input data. The design may be directly input in a suitable processing system (e.g. a cutter machine), or indirectly used (e.g. stored or transmitted to a remote production location), and eventually a customized splint will be prepared.

It was found that the design of the customized splint may be enhanced if even further input parameters are used, which are not obtained directly from the 2D image. To that end, in a further embodiment of the present invention, the further input parameters comprise one or more subject related parameters selected from the group of: gender, length, weight and age (or parameters derived therefrom such as body mass index, BMI). Additionally, or alternatively, in an embodiment of the present invention, the additional input parameters comprise one or more injury related parameters, such as type and/or position of a fracture.

In a further group of embodiments, the predetermined model of the body part relates the first and further input parameters to a predetermined set of 3-D dimensions of the body part using a plurality of body part indices. This allows to provide the customized shape for the thermoplastic material sheet directly and with sufficient accuracy. The predetermined model was verified to demonstrate sufficient accuracy of the relationship between 2-D image information and 3-D geometries. For this verification data from fifty people with different ages and genders were collected. Some specific indices were marked for which immobilization of an injured limb is required in addition to other indices which are used for designing the overall shape of the splint. Appropriate splints for any fracture can be designed using an associated predetermined model taking into account a limited number of dimensions (or input parameters) of each patient's body part. In the exemplary embodiment of taking an image of the arm, hand sizes of important points are calculated or determined from the 2D image. Specific points associated with a hand or wrist fracture e.g. include one or more of Palm Crease point, Wrist Crease point, tip and web points and some specific points on the arm (see also the 2D image of Fig. 1 and the distal image in Fig. 2).

In addition to the first and further input parameters, some vertical and horizontal measurements were performed as well to verify the predetermined model. Vertical measurements included 2-D sizes and horizontal measurements included both 2-D (using the captured 2D image) and 3-D sizes (measuring the perimeter of that index). In order to find the best equation fitted to these first and further input (the 'golden indices') to calculate 3-D sizes from 2-D sizes, 2-D indices which have best correlations with each of these golden indices are determined. Correlation analysis on the existing data provided from the fifty people data set revealed that in addition to indices, some further controlling parameters including the gender and the body mass index (BMI) of the patient affect this relationship, and hence these are included in one or more of the further embodiments as discussed above. The correlation analysis shows that gender is an important input factor. Therefore, a predetermined model was built for distinguished gender. In addition to the geometries of different

parts, some parameters including the height and the weight of the patient can also be introduced to enhance the predetermined model to extract the 3-D geometries using 2-D sizes. Using linear regression analysis with the best correlated components, the resulted equations for 2-D to 3-D mapping were extracted. The best correlated first and further input parameters and further

controlling parameters for each of golden indices are listed in Table 1.

Table 1. Correlated indices for both genders

| | Male | Female |
|---------------------------|--------------------------------|---|
| Palm Line | Palm line, Wrist line | Palm line |
| Wrist Line | Wrist Line | Wrist line |
| 1 st Arm Point | 1 st Arm Point | 1 st Arm Point, 2 nd Arm point, 3 rd Arm point |
| 2 nd Arm Point | 2 nd Arm Point, BMI | 2 nd Arm point |
| 3 rd Arm Point | 3 rd Arm point, BMI | 1 st Arm Point, 2 nd Arm point, 3 rd Arm point |

The resulting predetermined model as used in the present invention embodiments will result in reduced complexity in designing a customized splint using just one 2-D image. Using these further controlling parameters and also independent variables, the equations relating 3-D to 2-D sizes can be found. These equations form e.g. the predetermined model, and enable to use a single 2-D image to extract 3-D geometric parameters in a sufficiently accurate manner. Table 2 summarizes the relationships for each of the body part indices or golden indices.

Considering the average error presented in Table 2 and a tolerable error range for the thermoplastic materials, the present invention method embodiments even outperform its 3D-scanning counterpart known from the prior art by reducing cost, technical complexity.

Table 2. Resulted equations and associated error

| Parameter | Equation | | Average Error (mm) |
|---------------------------|---------------------------|----------------------------------|--------------------|
| | Male | Female | |
| Palm Line | $87.685+0.01P+0.117W$ | $46.524+0.253P$ | 3.64 |
| Wrist Line | $94.732+0.177J$ | $104.955+0.139J$ | 3.96 |
| 1 st Arm Point | $42.638+0.354A1$ | $16.446+0.524A1-0.217A2+0.133A3$ | 4.49 |
| 2 nd Arm Point | $88.034+0.224A2+1.676BMI$ | $73.453+0.307A2$ | 7.38 |
| 3 rd Arm Point | $99.964+0.206A3+2.105BMI$ | $27.117+0.541A1-0.342A2+0.344A3$ | 5.6 |

In one specific embodiment of the present invention, the 2D image of the body part is obtained using a 2-D camera. 2-D cameras are commercially available and are much less costly compared to e.g. 3-D cameras. A (high resolution) 2-D image taken from a commercially available 2-D camera is sufficient for extracting 3-D geometric parameters of the body part.

Fig. 4 shows an example of a sheet of thermoplastic material resulting from applying the present invention embodiments and outputted from the output unit 5 having a customised shape e.g. for an arm. The central hole in this example thermoplastic splint is used for inserting a thumb. Fig. 5 shows an example of a splint customized and applied on an arm applying the present invention embodiments. In an even further embodiment of the present invention, the 3D geometric parameters of the customized splint take into account a first air gap between two ends of the splint and additionally or alternatively a second air gap between the customized splint and the body part. The first and second air gaps are two different types of air gaps, both of which are considered when designing the splint using the present invention embodiments. The first air gap is the gap between the two ends of the splint (see the air gap between two ends of the splint in Fig. 5) when put on the arm which is necessary in order for the physician to open or to perform an inspection in the splint or in the body part at a later stage. The second air gap is a gap between the splint and the skin of the body part to avoid potential skin problems such as a pressure sore which is a sore that develops on the skin under the splint due to excess pressure on one area. In some situations, when the pressure inside the splint builds up, it can even cause damage to the muscles, nerves or blood vessels in the area covered by the cast. Hence both types of air gaps are taken into account in the present invention embodiments. Since thermoplastic materials have stretchable characteristics, a reasonable amount of error in calculating the 3D dimensions is tolerable anyway, which error is compensated by the stretchiness of the thermoplastic material. In this further embodiment, the air gap, which e.g. is in the range of 0.5 cm to 1 cm, and at least has a positive error margin larger than zero, allows for a more comfortable fit of the customizable splint to the patient, and for a comfortable splint removal. Errors in the 3D geometric parameters, resulting in a slight increase in the gap size, are furthermore tolerable and will not cause a problem in immobilization of a fracture.

Fig. 3 shows a schematic diagram of a system for designing a customized splint for a body part according to an embodiment of the present invention. The schematic diagram shows a system for designing a customised splint for a body part from a sheet of thermoplastic material, comprising an image input device 4 arranged to obtain an image of the body part, and a processing unit 2 connected to the image input device 4, the processing unit 2 being arranged to execute any one of the method embodiment described herein. For this, the processing unit 2 is connected to a memory unit 3, e.g. a database, which stores data including the predetermined model of the associated body part, and to an output unit 5, e.g. a machine to form the thermoplastic material sheet. The image input device 4 is e.g. a 2-D camera. By integrating these components, and possibly further components, such as a cutting machine, a fully or partially automated splinting system can be realised which can easily be used locally, e.g. in an emergency room environment, because of the small physical volume of the system.

The present invention has been described above with reference to a number of exemplary embodiments as shown in the drawings. Modifications and alternative implementations of some parts or elements are possible, and are included in the scope of protection as defined in the appended claims.

Claims

1. A method of designing a customised splint (1) for a body part from a sheet of thermoplastic material (6) wherein the method comprises:
5 obtaining a 2-dimensional (2-D) image of the body part,
extracting 3-dimensional (3-D) geometric parameters of the customized splint (1) using 2-D image information from the obtained 2-D image,
wherein extracting of the 3-D geometric parameters comprises:
10 extracting a smallest body part width (WP) along a length direction of the imaged body part as a first input parameter,
dividing the image into a distal image part and a proximal image part along the length direction using the first input parameter,
extracting further input parameters (FL, P, W, A1, A2, A3) from the distal and proximal image parts,
15 using the further input parameters (FL, P, W, A1, A2, A3) and a predetermined model of the body part to obtain the 3D geometric parameters, and
translating the obtained 3D geometric parameters to a customized shape of the sheet of thermoplastic material (6).
- 20 2. The method according to embodiment 1, wherein extracting further input parameters comprises:
determining a centre point (P) of the body part using boundary scanning from the distal image part,
determining a major reference position (W) of the body part relative to the determined centre point (P).
- 25 3. The method according to embodiment 2, wherein extracting further input parameters further comprises
determining tip and web points of the body part as local maxima and minima distances relative to the major reference position (W) using boundary tracing in the distal image part.
- 30 4. The method according to embodiment 2 or 3, wherein extracting further input parameters comprises
image processing of the distal image part for detecting creases, and
determining further input parameters from the detected creases.
- 35 5. The method according to any one of embodiments 1-4, wherein extracting further input parameters comprises image processing of the proximal image part.

6. The method according to any one of embodiments 1-5, wherein the method further comprises manufacturing the customized splint (1) using the 3D geometric parameters as input data.
- 5 7. The method according to any one of embodiments 1-6, wherein the further input parameters comprise
one or more subject related parameters selected from the group of: gender, length, weight, age.
8. The method according to any one of embodiments 1-7 wherein the further input parameters
10 comprise
one or more injury related parameters, such as type and/or position of a fracture.
9. The method according to any one of embodiments 1-8, wherein the predetermined model
of the body part relates the first (WP) and further input parameters (FL, P, W, A1, A2, A3) to a
15 predetermined set of 3D dimensions of the body part using a plurality of body part indices.
10. The method according to embodiment 9, wherein the body part is an arm, and the body
part indices comprise a palm line (P), a wrist line (W), a first arm point (A1), a second arm point
(A2) and/or a third arm point (A3).
- 20 11. The method according to embodiment 10, wherein one of the further input parameters is a
determined finger length (FL), and a first distance between the wrist line (W) and the first arm point
(A1) and a second distance between the first arm point (A1) and the second arm point (A2) is equal
to the finger length (FL), and a third distance between the second arm point (A2) and the third arm
25 point (A3) is equal to half the finger length (FL).
12. The method according to any one of embodiments 1-12, wherein the 2D image of the body
part is obtained using a 2-D camera (4).
- 30 13. The method according to any one of embodiments 1-12, wherein the 3D geometric
parameters of the customized splint (1) take into account a first air gap between two ends of the
customized splint (1) and additionally or alternatively a second air gap between the customized
splint (1) and the body part.
- 35 14. A system for designing a customised splint (1) for a body part from a sheet of thermoplastic
material (6), comprising
an image input device (4) arranged to obtain an image of the body part, and
a processing unit (5) connected to the image input device (4), the processing unit (5) being arranged
to execute the method according to any one of embodiments 1-13.

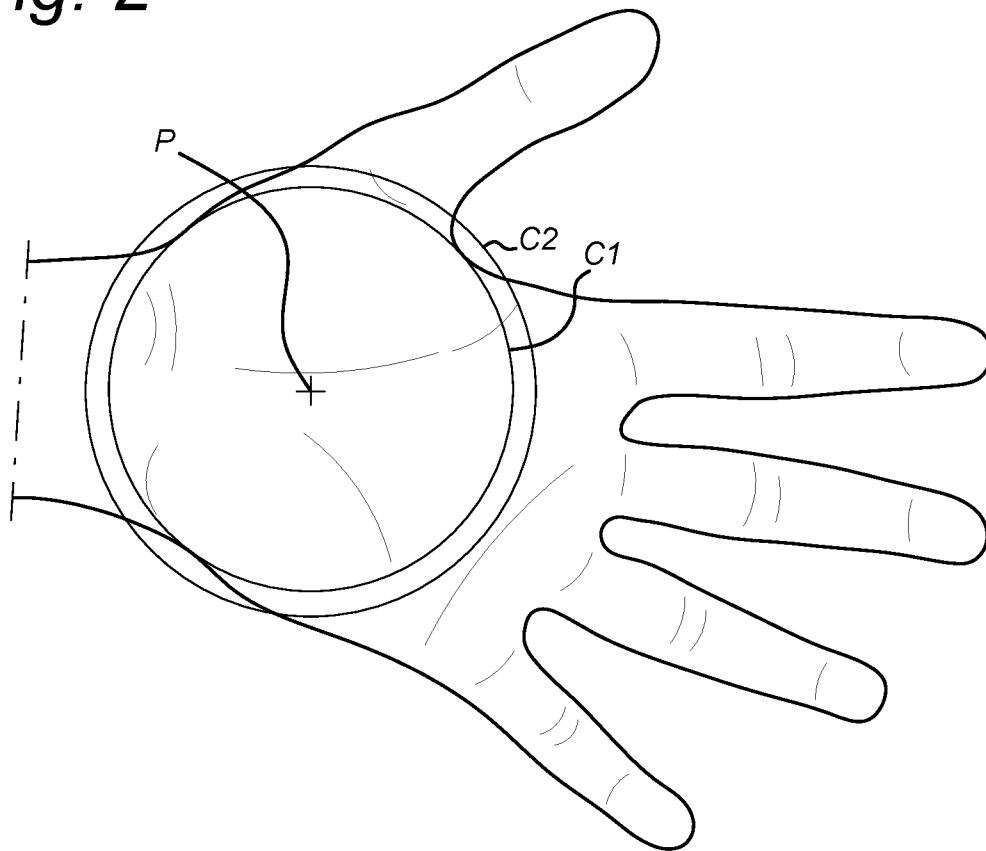
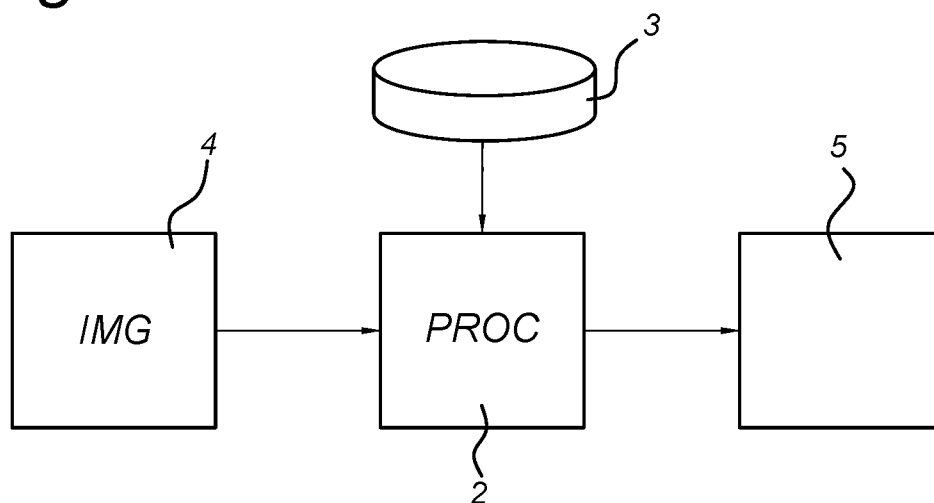
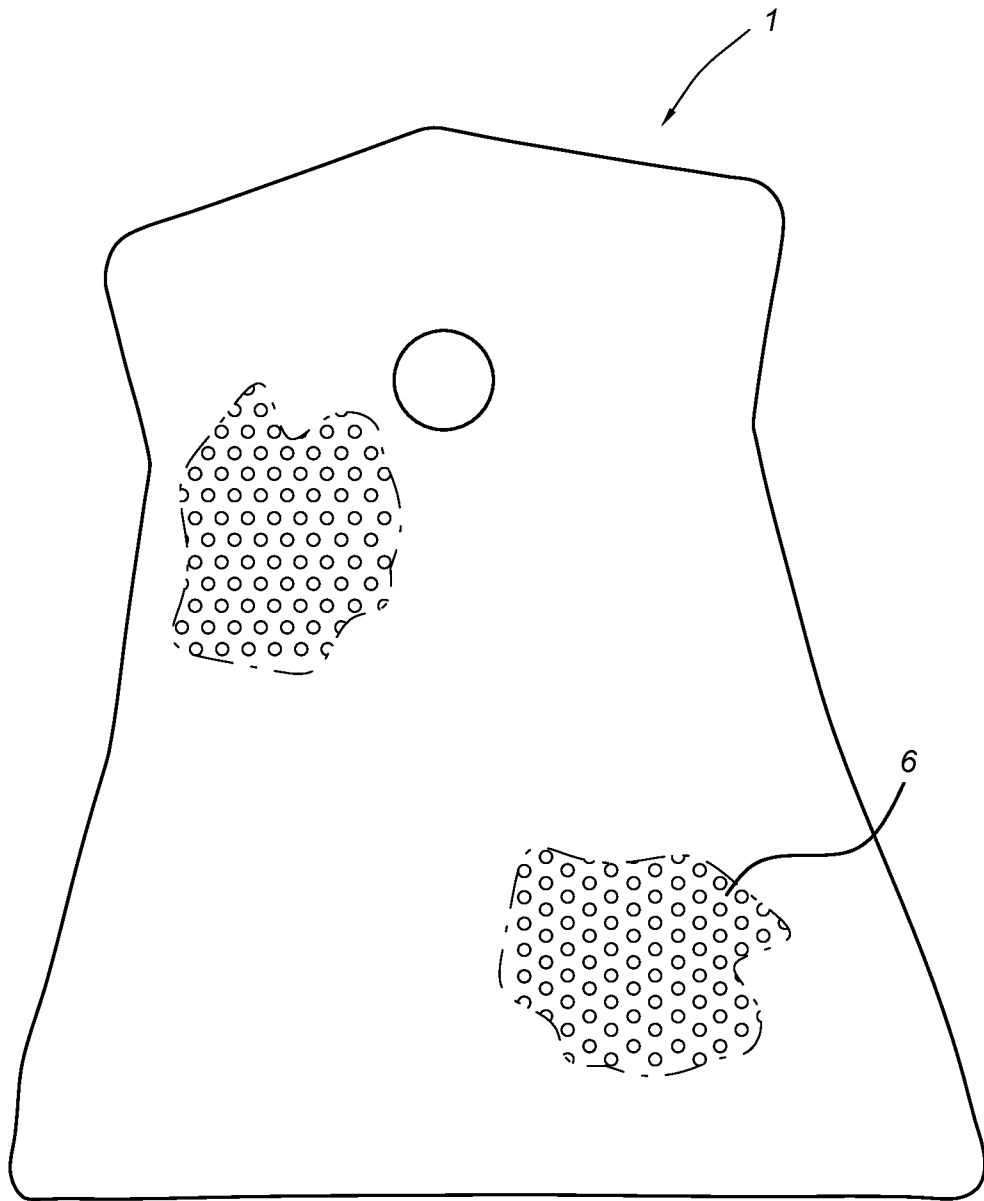
Fig. 2*Fig. 3*

Fig. 4

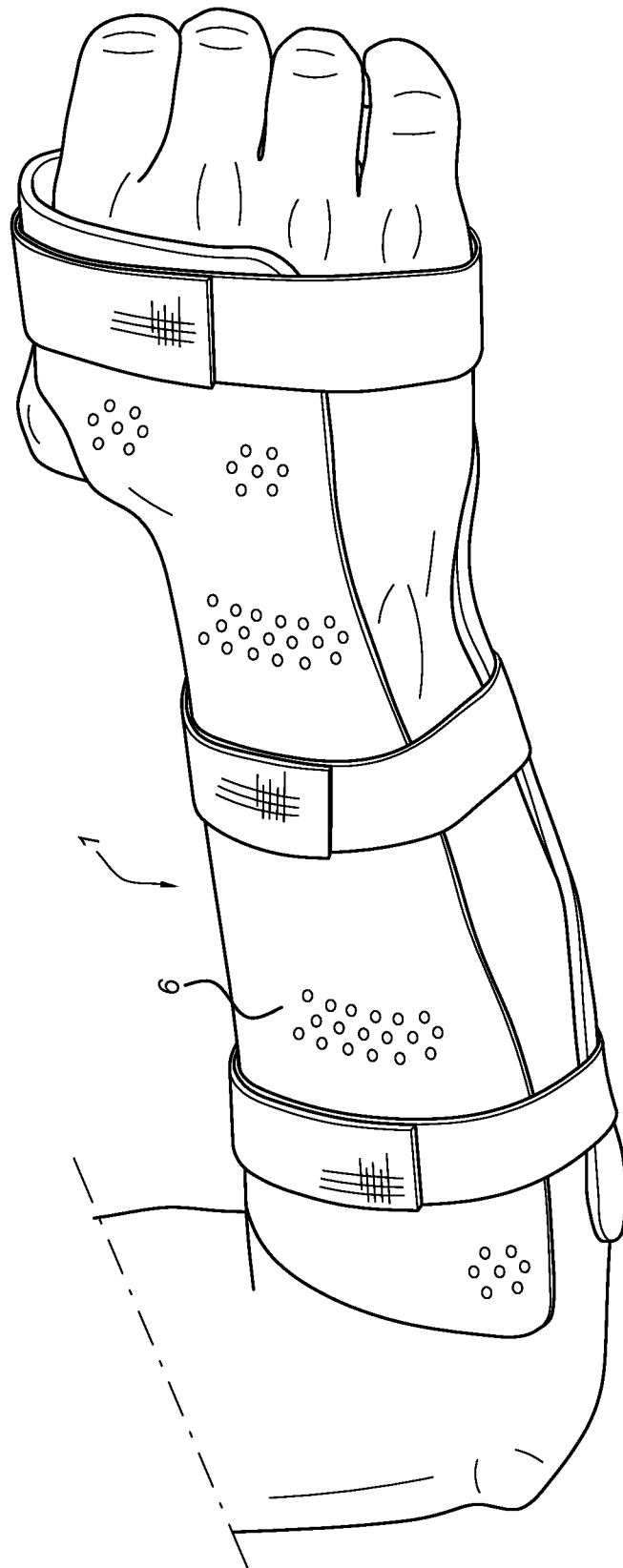


Fig. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/NL2018/050513

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F5/058
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)
A61F

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. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|---|-----------------------|
| A | US 2013/317789 A1 (SUMMIT SCOTT [US] ET AL) 28 November 2013 (2013-11-28) [0045] - [0048] ----- | 1-14 |
| A | W0 2015/032006 A1 (SHABAH ABD0 [CA]) 12 March 2015 (2015-03-12) page 22, second paragraph ----- | 1-14 |
| A | US 2014/142486 A1 (SUMMIT SCOTT [US] ET AL) 22 May 2014 (2014-05-22) [0050] - [0053] ----- | 1-14 |



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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"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

4 December 2018

Date of mailing of the international search report

19/12/2018

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/NL2018/050513

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---------------------|-----------------------------|--------------------------|
| US 2013317789 | A1 | 28-11-2013 | NONE |
| ----- | | | |
| WO 2015032006 | A1 | 12-03-2015 | CA 2923774 A1 12-03-2015 |
| | | US 2016213320 A1 28-07-2016 | |
| | | WO 2015032006 A1 12-03-2015 | |
| ----- | | | |
| us 2014142486 | A1 | 22-05-2014 | NONE |
| ----- | | | |