Title: BANDAGE FOR TREATMENT OF PRESSURE SORES, BEDSORES AND SIMILAR AILMENTS

Abstract: The product is a bandage for the treatment of pressure sores, bedsores and similar mainly human ailments. The bandage consists of an extensible, flexible textile material which serves primarily for the fixing of a pressure-relieving padding or pad which is placed over the affected area of the body. The padding or pad consists of soft, elastomeric material, especially polymer gel, which is moulded into a pad adapted to the area of the body in question. The bandage’s physical form is generally determined by the part of the body which is to be treated. In principle, all areas of the body can be treated. The product’s novelty consists in the textile material being moulded into the elastomeric material, such that the textile material enters as an integral fibre reinforcing in the pad. The moulded elastomeric material mainly constitutes limited areas of the bandage, so that the finished bandage has pads only opposite those parts of the body which are to be treated (relieved of pressure), while the other part of the bandage serves to fix the padding against the body.
DESCRIPTION

Designation
Bandage for treatment of pressure sores, bedsores and similar ailments.

Area of application
This invention is a bandage for the treatment of pressure sores, bedsores and similar mainly human ailments. The bandage consists of extensible, flexible textile material, the primary purpose of which is the fixing of a pressure-relieving pad or cushion which is placed over the affected (tender) area of the body. The pad or cushion consists of soft elastomeric material, especially polymer gel, which is moulded into a pad or cushion with moulded-in textile material in the elastomeric material, almost as a reinforcement, in a form adapted to the relevant area of the body. In general, the bandage’s physical form is determined by the area of the body on which the bandage is to be used. In principle, all areas of the body can be treated.

Known techniques
It is known that corns, bunions and related pressure sore problems on the feet can be treated with pressure-relieving dressings of a type consisting of a soft elastomeric pad which is held in position over the affected point on the foot with the aid of an elastic bandage or a plaster. The exposed and often highly pressure-sensitive part of the foot is thus protected against direct external pressure and against the irritation which, for example, can be caused by friction against the shoe, or, in the case of a pressure sore on the inner side of a toe, by rubbing against the neighbouring toe. The elastomeric insert or pad is usually made of a soft, almost viscous plastic. This plastic, which, for example, can consist of a silicone-based gel or another appropriate elastomer, is characterised by being extremely soft and workable, and ensures an optimal relief of pressure via this property and alleviation at the point of tenderness. The insert is usually shaped (prefabricated) as a flat circular piece which is placed over the tender point and fixed with the aid of the bandage as specified.

The known technique is usable for the treatment of a single bunion or a single pressure sore of limited physical extent, but in practice it is a problem that the bandage used to fix the pad is often very bulky, as a result of which the dressing itself can be a source of irritation and can, at worst, cause new pressure sores. The known treatments for relief of pressure are unsuitable for the prophylactic treatment of patients who are known to have a substantial risk of developing pressure sores, such as patients with diabetes, heart patients and patients with paralysis, because prophylactic use of the known forms of treatment will of its very nature assume a large number of individual dressings and pads on the foot at the same time, and this is of course not possible in practice without major inconvenience for the patient.

U.S. patent no. 5,823,195 describes a therapeutic stocking with two ankle inserts. The two ankle inserts protect the ankle and the area around it down to the heel against the formation of sores. The elastic stocking ensures an even pressure distribution over the relevant part of the foot. The ankle inserts are made of a silicone elastomer and are hydrophobic. For obvious reasons the therapeutic stocking is unsuitable for use in prophylactic treatment to prevent pressure sores on parts of the body other than just the ankles. The ankle inserts are placed in the therapeutic stocking as loose inserts. In practice this is done by the patient first putting on the stockings, after which the inserts are placed in them. The procedure is laborious and means that many patients, for example those with restricted ability to move or with paralysis, will have difficulty completing the task without assistance.
US patent no. 4,660,553 describes a bandage which consists of a textile material moulded into a silicone elastomer foam material so that the textile material is an integrated fibre reinforcement in the bandage. The bandage is made in an endless roll, and after hardening of the silicone elastomer, it can be cut or clipped into pieces suitable for the wound which is to be treated. The pieces of bandage are fixed over the wound with the aid of sticking plaster, or a traditional binding with e.g. gauze can be used. The pieces of bandage can also be used as inserts in surgical stockings or similar clinging items of clothing. In all cases this is thus a method suffering from the limitations and disadvantages specified above.

The technical problem to be solved
The invention arose out of the need to devise an elastomeric bandage of the type considered here with partially placed (as required) pressure pads and padding such that in principle, all areas of the body can be treated under the pressure-relieving treatment principle in question. Another aim was to find a solution which is not encumbered with the limitations and disadvantages which (cf. explanation above) are known with the other types of bandage.

The new technique
The novelty in the invention is that only a part of the textile material is moulded into the elastomeric material, and that the surplus part of the textile material encircles the pad (the elastomeric material), such that the finished bandage only has padding/cushions opposite the parts of the body which are to be treated (relieved of pressure), while the other part of the bandage serves to fix the padding/cushions against the body. The textile material is thus almost an integrated fibre reinforcement in the pad/cushion. The moulded elastomeric material comprises mainly well-delimited, well-defined areas of the bandage.

Under the invention, a polymer gel of the silicone type with a hardness of the order of 6-8 Shore A can be used with advantage as the padding material.

In a preferred embodiment, the elastomeric material can contain a drug which is released successively to the patient during the therapeutic treatment, either by diffusion, evaporation or otherwise dissolving. The drug in question, for example, can be a hormone, an antibiotic for the healing of sores, a morphine preparation for the treatment of pain, or a nicotine preparation to assist in giving up smoking.

The technical effect
By using the above new technique in connection with known types of bandage (textile materials), the intended universal applicability is obtained, as the bandage can easily be adapted/moulded to suit the relevant parts of the body. At the same time, the advantageous property is gained that the bandage occupies as little space as possible while “clinging” to the patient’s body, so that it inconveniences the patient as little as possible. The integral moulding of the textile material in the elastomeric material means that, in a way known in principle, the pad gains an advantageous fibre reinforcement required especially for the very soft polymer gel types. The method in question is also distinguished by permitting a rational, and thus economical, production of the bandage.

The product and particularly advantageous embodiments and details are explained individually in further detail below with references to the figures in the drawing.
Figures

Fig. 1 Shows a bandage according to the invention in collar form with moulded-on polymer gel padding, viewed obliquely from the side.

Fig. 2 A section of the same viewed from the side with the bandage unrolled.

Fig. 3 The same in cross-section along line A-A in Fig. 2.

Examples of embodiments

In the embodiment shown in Figs. 1-3, the bandage consists principally of a collar-shaped “stocking” 1 of extensible woven textile material 2. The material is of the type usually used for support stockings and similar clinging (thin) bandages. The “stocking” 1 has padding 3 in the form of a moulded-on pad of polymer gel, e.g. silicone. The hardness of this material is of the order of 8 Shore A, i.e., the padding material is extremely soft, almost viscous.

In the embodiment shown, the padding 2 is of a rounded, almost oval shape of a size corresponding to that area of the body on which pressure is to be relieved (or otherwise treated). Other padding shapes and thicknesses are of course also possible. The padding is moulded directly on to the bandage 1, so that the textile material 2 is moulded into the padding 3 (see transverse section drawing in Fig. 3). An appropriate reinforcing of the soft, and thus inherently physically weak, polymer material is thus obtained, and the technique enables a rational production process.

The collar-shaped bandage 1 with associated padding 3 is designed for use e.g. on an arm or a leg. The bandage is pulled like a stocking on to the body part in question. Bandages for other parts of the body are shaped and dimensioned accordingly, in principle following the same model as shown in the diagram. Bandages for feet and hands can be stocking-shaped or glove-shaped respectively. Bandages for knees, elbows, legs, arms, the torso etc. are mainly collar-shaped. In special cases the padding can be moulded in a spatially doubly curved shape which corresponds to the body part on which pressure is to be relieved. This is the case, for example, in the treatment of an elbow or a bunion.

The invention is not limited to the embodiment illustrated in the drawing and described above. Other combinations of materials and other designs for the individual components of the bandage are possible without departing from the framework of the invention, and the bandage’s area of application can be extended to areas other than that specified. For example, apart from relieving pressure, the bandage can also be used in connection with the treatment of pain (e.g. sporting injuries), the healing of sores, nicotine treatment (for people wanting to give up smoking), etc.
CLAIMS

1. Bandage of extensible, flexible textile material (2) for the treatment of pressure sores, bedsores and similar ailments, where the bandage serves primarily for the fixing of a pressure-relieving pad or cushion (3) which is placed over the affected (tender) area of the body, and where the pad or cushion consists of a soft, elastomeric material, especially polymer gel, which is moulded into a pad or cushion shape adapted to the relevant area of the body, with the textile material (2) moulded into the elastomeric material (3) almost as a reinforcement, characterised by only a part of the textile material being moulded into the elastomeric material (3), and that the surplus textile material encircles the pad (3), such that the final bandage has padding/cushions only opposite those parts of the body which are to be treated (relieved of pressure), while the other parts of the bandage serve to fix the padding/cushions to the body.

2. Bandage as defined in claim 1, characterised by the polymer gel used being of an appropriate, i.e. approved for skin contact, type of silicone with a hardness of the order of 6-8 Shore A.

3. Bandage as defined in claim 2, characterised by the polymer gel used being a two-component silicone from the company BAYER, type RTV 5005, mixed in the ratio 5:6 before moulding.

4. Bandage as defined in claim 1, characterised by the moulding of the silicone occurring in a closed shaped cavity in which the textile material (2) is inserted in advance, and by the filling of the shaped cavity with silicone by pressure injection (spray moulding process) in a manner already known in principle.

5. Bandage as defined in claim 1, characterised by the extensible bandage material (2) consisting of woven or knitted textile material of the (thin) type traditionally used for surgical stockings and similar bandage products.

6. Bandage as defined in claim 5, characterised by the bandage (1) having the form of a closed collar, for example for use as a dressing about the chest or abdomen of a patient, for example in the treatment of bedsores, or the bandage in analogous manner having a shape and size adapted to the part of the body to be treated with the elastomeric padding/cushions (3) moulded into the areas of the bandage opposite the tender parts of the body where the bandage is applied.

7. Bandage as defined in claim 1, characterised by the elastomeric material containing a drug which is successively released to the skin during the therapeutic treatment, either by diffusion, evaporation or otherwise dissolving.

8. Bandage as defined in claim 7, characterised by the drug in question being a hormone, an antibiotic e.g. for the healing of sores, a morphine preparation for the treatment of pain in combination with the soothing effect of the padding, or other appropriate medication.
### INTERNATIONAL SEARCH REPORT

**International application No.**

PCT/DK 01/00526

#### A. CLASSIFICATION OF SUBJECT MATTER

**IPC7: A61F 13/00 // A61F 5/30**

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)

**IPC7: A61F**

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

SE, DK, FI, NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

**EPO-INTERNAL, WPI DATA, PAJ**

#### C. DOCUMENTS CONSIDERED TO BE RELEVANT

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

* Special categories of cited documents
  *A* document defining the general state of the art which is not considered to be of particular relevance
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**Date of the actual completion of the international search:**

3 December 2001

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